Original Paper

Establishment and Optimization of a Patient-Reported Outcome–Based Electronic-Diary for Symptoms Evaluation in Patients With Gastroesophageal Reflux Disorder: Prospective Cohort Study

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Abstract

Background: Gastroesophageal reflux disease (GERD) symptoms substantially impair patients' quality of life. The use of patient-reported outcome (PRO) instruments for symptom measurement has been advocated by regulatory authorities. However, current tools for GERD symptom evaluation are limited by recall bias. To improve the real-time characterization of GERD symptoms, we developed an electronic diary (e-diary) for daily symptom monitoring.

Objective: This study aimed to develop and optimize a PRO-based e-diary for GERD symptom evaluation and to examine the effect of symptom frequency on adherence.

Methods: The GERD e-diary evaluated 8 daytime (acid regurgitation, cough, heartburn, sour taste in the mouth, hiccups, hoarseness, dysphagia, and chest pain) and 2 nighttime symptoms (acid regurgitation and cough) for 8 consecutive weeks. Adherence, defined as the daily completion rate of e-diary, was analyzed and optimized across three stages: (1) no reminder, (2) sending reminder SMS text messaging upon the detection of missing data (no reminders during the first 3-5 days after enrollment), and (3) immediate installation of reminder system at enrollment. Weekly symptom frequency was calculated as the sum of symptomatic days per week. Multiple regression analyses were performed to examine the effects of system optimization and symptom frequency on adherence after controlling for confounders.

Results: A total of 138 patients with GERD (70 men, 68 women; mean [SD] age 52.9 [12.3] years) were recruited. At the first stage, the adherence was 47.2%, 40%, and 57.6% for nighttime, daytime, and overall symptoms. System optimization significantly improved the adherence of nighttime symptoms by 12.5% (95% CI 3.7-21.3) and 10.9% (95% CI 2.6-19.2), daytime symptoms by 21.7% (95% CI 14.2-29.2) and 20.8% (95% CI 13.7-27.9), and overall symptoms by 16.5% (95% CI 9.8-23.2) and 18.5% (95% CI 12.2-4.8) in the second and third stages, respectively. Symptom frequency was positively associated with adherence, increasing by 0.7% (95% CI 0.6-0.8) for overall symptoms and 0.9% (95% CI 0.7-1) for both daytime and nighttime symptoms per additional symptom frequency. Adherence gradually decreased along the study period.

(first vs eighth week: nighttime 80.1% vs 61.5%, β=−18.6, 95% CI −26.9 to −10.3; daytime 85.1% vs 66.8%, β=−18.3, 95% CI −25.6 to −11; overall 95.1% vs 78%, β=−17.2, 95% CI −23.5 to −10.9).

Conclusions: The adherence of the GERD e-diary can be optimized by using SMS text messaging reminders. Higher symptom frequency was associated with increased adherence, although engagement declined over time. This innovative PRO-based e-diary with prolonged recording provides a real-time, prospective tool that overcomes the recall and ecological biases inherent in traditional short-term retrospective GERD symptom assessments. This advancement empowers patients through improved self-awareness and provides physicians with precise, long-term data, facilitating tailored therapeutic interventions and supporting personalized GERD management.

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Keywords: adherence; e-diary; gastroesophageal reflux disease; GERD; symptom frequency; system optimization

Introduction

Gastroesophageal reflux disease (GERD) is a common disorder affecting approximately 20% of the general population [1]. GERD symptoms, including typical (heartburn and acid regurgitation) and atypical (cough, chest pain, sour taste in the mouth, hoarseness, dysphagia, and hiccups) symptoms, would bring significant burdens on patients' quality of life, reduce work productivity, and increase considerable medical resources worldwide [2-6]. As a symptom-driven disease, GERD should be evaluated for the presence, frequency, and severity of bothersome symptoms [1]. However, patient-reported clinical management outcomes often remain unsatisfactory, with more than 50% of patients continuing to experience bothersome symptoms despite proton pump inhibitor therapy [7]. This underscores the need for more nuanced approaches to symptom assessment and management.

Patient-reported outcomes (PROs) are the most direct and measured instrument for evaluation, an approach advocated by the Food and Drug Administration of the United States to assess treatment efficacy [8]. In GERD research, PROs have been used to evaluate the symptomatic improvements after acid-suppressant drugs, such as proton pump inhibitors or histamine-H2-receptor antagonists [9-11]. PROs have also been used in long-term studies to evaluate symptom resolution after surgery and endoscopic interventions and to assess improvements in quality of life [12-14]. However, most previous studies relied on questionnaires that required patients to recall symptoms over prolonged periods, possibly leading to recall bias. Furthermore, during outpatient evaluation and follow-up in patients with GERD, important information about the time course of symptom occurrence and relief is still limited because the caring physicians typically assess bothersome symptoms after weeks or even months of treatment. Notably, it has been reported that a 30-day recall of self-reported urinary incontinence is impaired and can be associated with demographic and psychosocial characteristics [15]. Patients with GERD are expected to face similar situations when using questionnaires to recall their symptoms [16-18]. Therefore, daily assessments of the GERD symptoms would provide a better understanding of the natural course of GERD symptoms and potentially alleviate the recall bias. Although patients with chronic gastroenterological diseases express strong interest in using mobile health apps for disease management, real-world adherence remains low, with high dropout rates [19]. Some studies report that up to 80% of participants engage only minimally or discontinue regular use, with retention rates dropping to as low as 3.9% after 15 days [20-22]. Existing GERD questionnaires also face limitations: their perceived impracticality for routine clinical use, along with challenges inherent to traditional paper-based symptom tracking—such as recall bias, inconsistent formatting, and poor adherence leading to incomplete or inaccurate data—collectively impede accurate and continuous symptom assessment for both patients and clinicians [23]. Given the high patient interest in digital health solutions, there is a critical need for novel mobile tools capable of overcoming these traditional limitations [24]. Although there are some smartphone apps for gastrointestinal disease, including GERD, available in the market, no app is compliant with the 2022 American College of Gastroenterology Guideline and not designed for physicians' management of GERD symptoms, and most of the apps are not evidence based [24-26].

To overcome recall bias and better address the progression and regression of GERD symptoms, in this study, we developed an e-diary for recording GERD symptoms. As low adherence in GERD diary recording would potentially limit the accountability of the e-diary, affecting clinical assessments and the associated outcomes, we tried to develop a strategy to enhance the 8-week adherence using the e-diary. Furthermore, our clinical observations and existing literature suggest a strong link between symptom severity and recording motivation: patients experiencing more frequent or intense symptoms typically demonstrate greater adherence and accuracy in documentation [27,28]. Therefore, we subsequently tested that higher symptom frequency would be associated with increased adherence to e-diary recording. The objective of the study was to examine the effects of symptom frequency and the degree of system optimization on weekly adherence, with the hypothesis that after adjusting for potential confounders, higher symptom frequency and greater system optimization would be associated with better weekly adherence. This will serve as a basis for developing strategies to improve patient adherence in completing the e-diary, thereby enhancing the clinical validity of the e-diary for GERD symptoms.

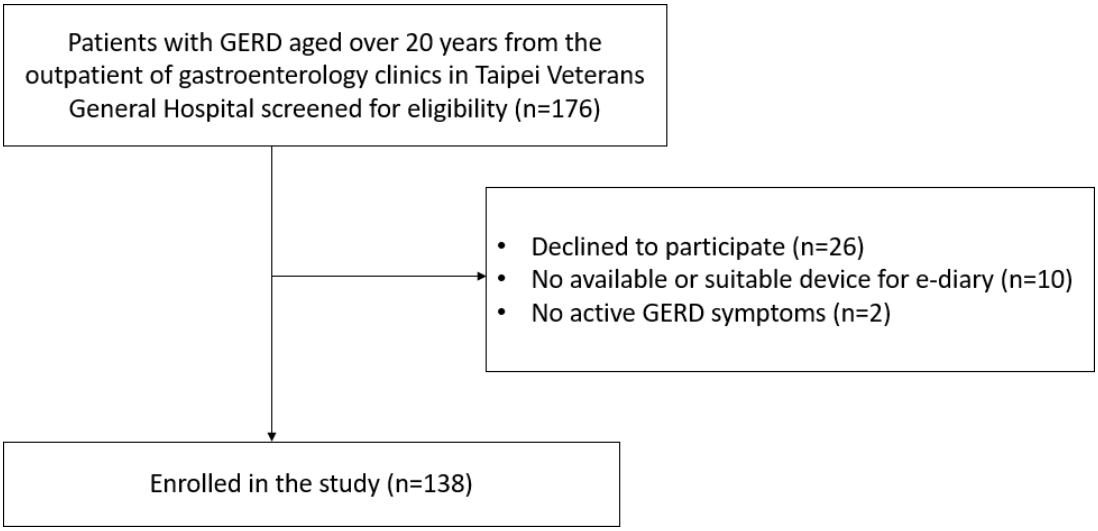
Methods

In this study, we followed the EQUATOR (Enhancing the Quality and Transparency of Health Research) guidelines using the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) checklist [29].

Study Design and Participants

The study was a prospective observational cohort study. From October 2021 to January 2023, consecutive adults (aged ≥20 y) with GERD were recruited from the outpatient clinics of gastroenterology in Taipei Veterans General Hospital, a tertiary medical center in northern Taiwan. Eligible participants presented with either typical (acid reflux or heartburn) or atypical symptoms (hoarseness, throat discomfort, cough, or chest pain) for at least 3 months. Heartburn or regurgitation should be noted for 4 days or more during the 7 days before the first visit. Patients who expressed interest and consented to daily symptom recording using the GERD e-diary were enrolled. A trained research assistant installed the GERD e-diary on the mobile phones of participants and provided instructions for use. These patients were asked to complete the GERD e-diary on a daily basis for 8 weeks. One or two follow-up visits in gastroenterology clinics would be arranged. To minimize potential selection and information bias, consecutive eligible patients attending the outpatient gastroenterology clinics were approached, and all data were prospectively recorded using standardized digital forms. As symptom data were collected directly from patients through an electronic diary (e-diary), recall bias was substantially reduced compared with paper questionnaires. The study size (n=138) was determined pragmatically according to the expected recruitment capacity within the 15-month study period and the pilot nature of this observational study. No formal sample size calculation was performed, consistent with the exploratory objectives. Patient flow from screening to analysis is summarized in Figure 1, which illustrates the number of patients invited (n=176), enrolled (n=138), and completing the 8-week follow-up, together with the reasons for exclusion.

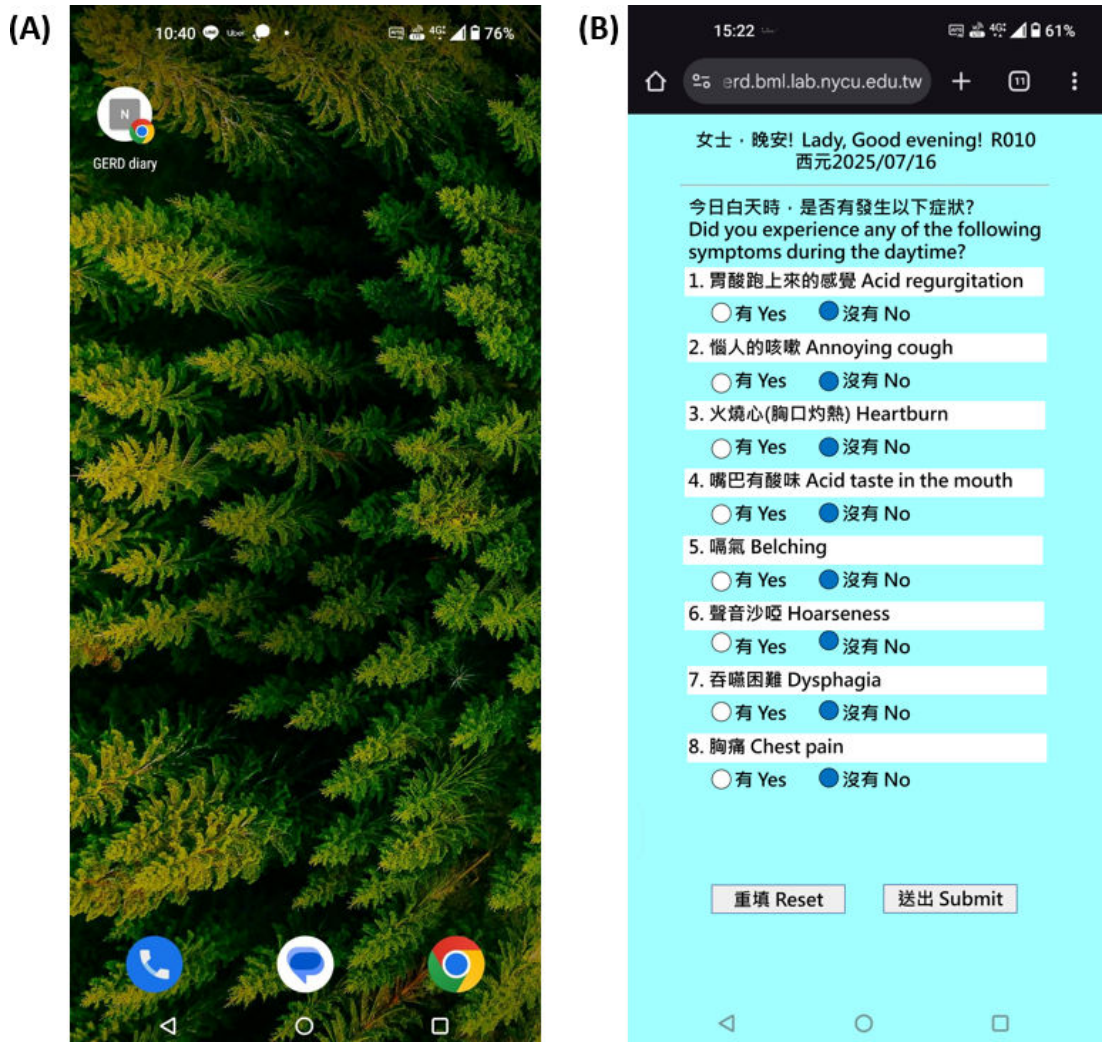
Figure 1. Patients flowchart. GERD: gastroesophageal reflux disease.



The GERD E-Diary

The web-based GERD e-diary was designed to record both nighttime and daytime GERD symptoms. Patients were asked to fill out the e-diary twice a day. In the morning, they were asked to fill in nighttime symptoms during the previous night, while in the evening, they were asked to record daytime symptoms that occurred during the concurrent day. The GERD e-diary was designed to assess 8 daytime symptoms (acid reflux, cough, heartburn, sour taste in the mouth, burping, hoarseness, dysphagia, and chest pain) and 2 nighttime symptoms (acid reflux and cough). The choice of these GERD symptom records was based on the Modified Reflux Symptom Questionnaire–Electronic Diary, which proved to be a reliable and valid PRO instrument [30]. After completing the e-diary, educational or inspiring messages would be randomly displayed to encourage continued participation. Although it was a web-based e-diary, we installed it as a smartphone shortcut icon that functioned like a mobile app, as Figure 2 showed.

Figure 2. Interface of the web-based gastroesophageal reflux disease (GERD) e-diary used in this cohort study conducted at Taipei Veterans General Hospital, Taiwan (October 2021 to January 2023). The shortcut icon was added to patients' smartphones, providing an app-like interface for direct daily input of GERD symptoms. (A) Home screen appearance; (B) symptom entry interface.



Optimization of the GERD E-Diary

Optimization of the e-diary system was developed with 3 stages. The first stage was initiated without reminders to the patients with GERD to complete the twice-daily questionnaire on mobile phones (October 7, 2021, to January 17, 2022; n=9). As most of these patients (n=5) failed to fill in the questionnaire (defined as completing <60% [range: 46.4%-57.1%] of the overall symptom diary) in the first stage, we designed an SMS text messaging reminder in the second stage (January 18, 2022, to June 30, 2022; n=51). In this stage, the system would automatically check at noon and 10 PM each day to determine whether the patients had filled out the diary. Once an unfilled e-dairy was detected, an SMS text message was sent to the patients' mobile phones. If no entries were submitted for 3 consecutive days, an additional notification was sent to the research team to contact the patients. During the second stage, the reminder function was activated manually, resulting in no reminder function during the 3 to 5 days after enrollment. In the third stage of system optimization (July 1, 2022, to January 19, 2023; n=78), the reminder system was fully automated and activated immediately upon enrollment, eliminating the need for manual setup.

Adherence of the GERD E-Diary and Variables Affecting the Completeness of the E-Diary

The GERD e-diary adherence was evaluated by measuring the overall weekly symptom adherence rate, which was the number of days or nights symptoms filled out per week divided by 7. The overall symptom adherence rate was further categorized into nighttime (weekly nighttime adherence rate: number of nights filled out per week/7) and daytime (weekly daytime adherence rate: number of days filled out per week/7). The potential independent variables affecting the adherence rate, including the frequency of GERD symptoms (weekly total symptom days: 10 symptoms per day×7 days=70 symptom days, ranging from 0 to 70) and the system optimization stage (3 stages, with higher stage indicating greater optimization), as well as the other confounders (such as age, gender, smoking, alcohol consumption, and comorbidities [sleep disorders, mental illnesses, sleep apnea, chronic obstructive pulmonary disease, asthma, liver or kidney diseases, cardiovascular diseases, diabetes mellitus, inflammatory bowel disease, central nervous system

disorders, functional gastrointestinal disorders, and malignant diseases]) were measured.

Statistical Analysis

Descriptive statistics were performed for categorical variables as case numbers and percentages and means and SDs (including range) for continuous variables. The sampling method was clarified as convenience sampling of eligible outpatients. Any diary entry that was not completed on a given day was classified as nonadherence for that specific time point. As adherence was one of the key outcomes of interest, incomplete entries were interpreted as reflecting nonadherent behavior rather than ignorable missingness. Generalized estimating equations or multiple linear regression models were constructed to examine the effects of system optimization stage and weekly symptom frequency on adherence rates (nighttime, daytime, and overall). Independent variables included system optimization stage (categorical, 3 levels), symptom frequency (continuous), and potential confounders, such as age, gender, smoking, alcohol consumption, and major comorbidities. For repeated weekly adherence values across the 8-week observation period, a repeated-measures analysis with week as the within-subject variable was performed to assess temporal trends. All results are reported as β coefficients with corresponding 95% CIs and *P* values. Two-tailed significance was defined as $P<.05$.

Ethical Considerations

The study was reviewed and approved by the Medical Ethics Committee of Taipei Veterans General Hospital (2021-05-012CC) and conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all eligible participants before data collection, covering both the collection of primary data and its secondary analysis. Participants were informed that they could withdraw from the study at any time without any impact on their future medical care. To ensure privacy protection, all data were deidentified using participant codes, and no identifiable information was disclosed. Participants received a reimbursement of TWD $500 (approximately US $16) for their participation in the study.

Results

Clinical Characteristics of Patients With GERD

A total of 138 patients with GERD (mean [SD] age 52.9 [12.3] y; range 24.4-78.4 y; 68 female patients) were enrolled. Approximately one-third (46/138, 33.3%) of patients displayed coexisting functional gastrointestinal disorders. The baseline characteristics and comorbidities are summarized in Table 1.

Table 1. Baseline demographic and clinical characteristics of 138 patients with gastroesophageal reflux disease enrolled from the outpatient gastroenterology clinics at Taipei Veterans General Hospital, Taiwan (October 2021 to January 2023).

Clinical characteristics	Values
Age (y), mean (SD); range	52.9 (12.3); 24.4-78.4
Female, n (%)	68 (49.3)
Smoking, n (%)	14 (10.1)
Alcohol, n (%)	30 (21.7)
Sleep disorders, n (%)	72 (52.2)
Mental illnesses, n (%)	7 (5.1)
Sleep apnea, n (%)	17 (12.3)
Chronic obstructive pulmonary disease, n (%)	2 (1.4)
Asthma, n (%)	14 (10.1)
Liver or kidney diseases, n (%)	15 (10.9)
Cardiovascular diseases, n (%)	38 (27.5)
Diabetes mellitus, n (%)	11 (8.0)
Inflammatory bowel disease, n (%)	5 (3.6)
Central nervous system disorders, n (%)	2 (1.4)
Functional gastrointestinal disorders, n (%)	46 (33.3)
Malignant diseases, n (%)	16 (11.6)

System Optimization and Effects of Symptom Frequency on Adherence

As presented in Table 2, during the first stage of system optimization, the nighttime symptom adherence rate was 47.2%. Implementation of the reminder system significantly increased adherence by 12.5% in the second ($P=.005$) and 10.9% in the third stages ($P=.01$). For daytime symptom reporting, the adherence rate in the first stage was 40.0%, which improved by 21.7% in the second ($P<.001$) and 20.8% in the third stages ($P<.001$). The overall adherence reporting in the first stage was 57.6%, with further increases of 16.5% in the second ($P<.001$) and 18.5% in the third stages ($P<.001$). For every additional symptom frequency, there was a significant increase of 0.9% in adherence for both daytime and nighttime symptom reporting and an increase of 0.7% for

overall symptom reporting (*P*<.001). These findings indicate that higher symptom frequency was positively correlated with participants' motivation to complete the GERD e-diary, suggesting that patients experiencing more frequent symptoms were more engaged in self-monitoring.

Table 2. Effects of system optimization and symptom frequency on adherence to the gastroesophageal reflux disease e-diary.[a]

Adherence (%)	β[b,c] (95% CI)	*P* value
Nighttime symptom		
System optimization (first stage)	47.2	
System optimization (second vs first stage)	+12.5 (3.7 to 21.3)	0.005
System optimization (third vs first stage)	+10.9 (2.6 to 19.2)	0.01
Symptom frequency	+0.9 (0.7 to 1)	<.001
Daytime symptom		
System optimization (first stage)	40	
System optimization (second vs first stage)	+21.7 (14.2 to 29.2)	<.001
System optimization (third vs first stage)	+20.8 (13.7 to 27.9)	<.001
Symptom frequency	+0.9 (0.7 to 1)	<.001
Overall symptom		
System optimization (first stage)	57.6	
System optimization (second vs first stage)	+16.5 (9.8 to 23.2)	<.001
System optimization (third vs first stage)	+18.5 (12.2 to 4.8)	<.001
Symptom frequency	+0.7 (0.6 to 0.8)	<.001

[a]Results derived from multiple linear regression models adjusted for potential confounders, including age, gender, smoking, alcohol consumption, and comorbidities.
[b]β=change in adherence in the second and third stages of system optimization compared with the first stage.
[c]β=change in adherence per additional symptom frequency.

Adherence Trends in GERD E-Diary Recording

Table 3 presents the weekly change in adherence rate among all enrolled patients with GERD. The nighttime symptom adherence rate was 80.1% during the first week and began to decrease significantly from the third week (71.5%; *P*=.04), reaching 61.5% by the eighth week (*P*<.001). For daytime symptom reporting, adherence was 85.1% in the first week and showed a significant decline beginning at the fourth week (76.0%; *P*=.01) and further to 66.8% by the eighth week (*P*<.001). Overall adherence followed a similar trend, starting at 95.1% in the first week, decreasing to 86.7% in the fourth week (*P*=.009), and dropping to 78.0% in the eighth week (*P*<.001). These results demonstrate a gradual decline in participant engagement with the e-diary over time, despite the implemented reminder optimization strategies.

Table 3. Weekly adherence trends of gastroesophageal reflux disease e-diary completion during the 8-week study period.

Symptoms and week	Adherence (%)	β[a] (95% CI)	*P* value
Nighttime symptoms			
1	80.1	N/A[b]	N/A
2	72	–8.1 (–16.4 to 0.2)	0.06
3	71.5	–8.6 (–16.9 to –0.3)	0.04
4	67.9	–12.2 (–20.5 to –3.9)	0.004
5	68.4	–11.7 (–20 to –3.4)	0.006
6	61.6	–18.5 (–26.8 to –10.2)	<.001
7	64.3	–15.8 (–24.1 to –7.5)	<.001
8	61.5	–18.6 (–26.9 to –10.3)	<.001
Daytime symptoms			
1	85.1	N/A	N/A
2	82.6	–2.5 (–9.8 to 4.8)	0.50
3	80.5	–4.6 (11.8 to 2.7)	0.22
4	76	–9.1 (16.4 to 1.8)	0.014
5	72	–13 (–20.3 to -5.8)	<.001

Symptoms and week	Adherence (%)	β[a] (95% CI)	*P* value
6	69.5	−15.6 (−22.9 to -8.4)	<.001
7	68.4	−16.7 (23.9 to −9.4)	<.001
8	66.8	−18.3 (−25.6 to −11)	<.001
Overall symptoms			
1	95.1	N/A	N/A
2	89.9	−5.3 (−11.6 to 1)	0.10
3	88.9	−6.2 (−12.5 to 0.1)	0.05
4	86.7	−8.4 (−14.7 to −2.1)	0.009
5	83.4	−11.7 (−18 to −5.4)	<.001
6	78.3	−16.9 (−23.3 to −10.6)	<.001
7	79.6	−15.5 (−21.9 to −9.2)	<.001
8	78	−17.2 (−23.5 to −10.9)	<.001

[a]β=β values representing the percentage change in adherence compared with the first week, with 95% CIs and *P* values derived from repeated-measures analysis.
[b]N/A: not available.

Comparison of GERD E-Diary With Previous GERD Evaluation Tools

The characteristics and differences between our current GERD e-diary study and previous GERD questionnaire studies are summarized in Table 4. This e-diary, using separate day and night assessments, can record 10 relevant GERD symptoms daily and also provide educational information.

Table 4. Comparison of patient-reported outcome (PRO) instruments for gastroesophageal reflux disease (GERD). The summary includes data entry frequency, number of symptoms recorded, and whether daytime and nighttime symptoms were separately assessed.

PRO instrument[a]	GRACI[b] [31]	Puhan et al [32]	GerdQ[c] [16]	RESQ-7[d] [33]	GERD e-diary
Data entry frequency	Daily	Daily	Weekly recall	Weekly recall	Daily
Number of symptoms recorded	5	3	6	13	10
Day and night recording	No separation[e]	Separately assessed[f]	No separation	Not assessed[g]	Separately assessed
Recording format	Paper	Paper	Paper	Paper	Electronic diary
Providing educational information	N/A[h]	N/A[h]	N/A[h]	N/A[h]	Yes

[a]Summary includes data entry frequency, number of symptoms recorded, and whether daytime and nighttime symptoms were separately assessed.
[b]GRACI: Gastroesophageal Reflux Disease Activity Index.
[c]GerdQ: Gastroesophageal Reflux Disease Questionnaire.
[d]RESQ-7: Reflux Symptom Questionnaire, 7 day recall
[e]No separation: daytime and nighttime symptoms recorded together.
[f]Separately assessed: daytime and nighttime symptoms recorded separately.
[g]Not assessed: no specific daytime or nighttime symptom assessment.
[h]N/A: not available.

Discussion

Principal Findings

In this study, we demonstrated that a GERD e-diary was successfully developed to record GERD symptoms twice daily (day and night) with relatively high adherence. Patients' adherence was significantly improved with the application of SMS text messaging reminders in the e-diary system. In addition, patients who experienced more frequent symptoms tended to demonstrate higher levels of adherence. While the overall adherence rate reached approximately 80% over the 8-week period, a gradual decline was observed over time. This PRO-based e-diary, which enables prolonged and continuous symptom recording, provides a real-time and prospective assessment framework that substantially reduces the recall and ecological biases associated with conventional short-term, retrospective GERD symptom evaluations. By facilitating structured, longitudinal monitoring, the system not only enhances symptom awareness for patients but also offers clinicians high-resolution, long-term data that support more customized therapeutic decisions and advance personalized GERD management.

Comparison With Prior Work

PRO measures are essential for evaluating both disease burden and treatment efficacy in GERD [6]. Several instruments have been developed to capture these outcomes. For example, the GRACI (Gastroesophageal Reflux Disease Activity Index) integrates patient diaries with structured nurse-led interviews, thereby reducing physician workload and minimizing assessor bias [31]. Puhan et al [32]

introduced a symptom diary that tracked heartburn frequency, severity, and antacid use over 4 to 6 weeks, achieving high adherence, with only 7.9% of patients completing fewer than 80% of entries. The GerdQ (Gastroesophageal Reflux Disease Questionnaire), a 6-item tool, facilitates diagnosis and management in primary care without the need for specialist referral [16]. Similarly, RESQ-7 (Reflux Symptom Questionnaire, 7-day recall) evaluates 13 GERD-related symptoms based on a 7-day recall period [33]. Despite their clinical value, most PRO tools have important limitations. They typically capture symptoms over short intervals (often 1 wk), which makes it difficult to assess temporal fluctuations in patients with intermittent symptoms. Relying on weekly recall instead of daily reporting also introduces bias, as patients tend to overestimate symptom intensity and underestimate frequency [34]. Daily PROs are generally more accurate, especially for variable symptoms [35], but even these prior studies fail to differentiate between daytime and nocturnal symptoms. This is a critical gap, as nighttime symptoms are common in GERD and strongly impact quality of life [36]. Additionally, many existing PROs record only a narrow range of symptoms, limiting their clinical comprehensiveness. Another concern lies in data collection methods. Traditional paper-based questionnaires are vulnerable to retrospective completion, which compromises accuracy. In contrast, electronic data entry systems can restrict both prospective and retrospective inputs, thereby reducing recall bias and improving data integrity [35]. To overcome these challenges, we developed a web-based GERD e-diary that records symptoms twice daily over an 8-week period. This approach provides a more reliable picture of symptom patterns, minimizes recall bias, and generates richer data for clinicians. Importantly, the e-diary also enhances patient awareness of their condition. Together, our GERD e-diary features improve the accuracy and comprehensiveness of GERD assessment, ultimately fostering greater confidence in management for both clinicians and patients.

In the first phase of building up the e-diary, the overall adherence rate was as low as approximately 40%. Therefore, we incorporated a reminder system into the e-diary and activated it upon the detection of missed entries. In the second stage, the reminder system became available only 3 days after enrollment, whereas in the third stage, it was activated immediately upon enrollment. Both optimization measurements would significantly improve overall symptom adherence to approximately 80%. Previous research supported the effectiveness of reminders in enhancing health-related behaviors. For example, a review of 11 randomized controlled trials (1999-2009) confirmed that reminder interventions significantly improved daily medication adherence compared to no-reminder controls [37]. Another study demonstrated that daily SMS text messaging reminders enhanced adherence to antiasthmatic treatment [38]. Similarly, email and letter reminders significantly improved colorectal cancer screening rates compared to usual care, with no difference between the 2 reminder types (email and letter) [39]. Furthermore, reminding patients and clinicians, especially those directed at patients, is an effective strategy to improve colorectal cancer screening rates among individuals who are not up to date with screening [40]. In line with these findings, our study demonstrated that incorporating SMS text messaging reminders substantially improved adherence to GERD e-diary recordings. Despite the favorable results, there seemed to be little difference between the second and third stages of system optimization, which might be due to the short time delay (3-5 d) of the incorporation of the reminding systems.

We also found that higher symptom frequency was associated with increased adherence. Similar observations had been reported in other diseases. For instance, patients with urinary incontinence who experienced greater voiding frequency exhibited higher adherence to voiding diaries [27]. Furthermore, in patients with seasonal allergic rhinitis, symptom recording adherence to an e-diary was significantly higher during the peak grass pollen season, which coincided with more intense allergic symptoms [28]. All observations suggested that more frequent and severe symptoms may be associated with enhanced awareness and stronger motivation to report their disease status to health care providers.

Despite relatively high adherence at the beginning phase, our study showed a gradual decline in adherence over the 8-week period. This trend was consistent with previous findings in other diseases. For example, patients with allergic rhinitis demonstrated a slow decline in e-diary completion from 90% in the first week, 80% to 90% in the second to sixth weeks, and 70% to 80% after the seventh week [28]. A separate study assessing voiding diaries among patients with urinary incontinence similarly reported that a 7-day diary posed a higher burden than shorter 2- or 3-day formats [41]. In addition, 3 respiratory clinical trials also demonstrated that adherence decreased over time after randomization [42]. All results suggested that adherence to long-term daily symptom recording might be challenging for the patients to complete the daily diary study.

To improve long-term adherence, several strategies might be considered. Providing additional information and education could be applied to promote better adherence in e-diary recording [28]. Reducing diary duration may also enhance patient compliance and minimize burden [41]. Additional methods to increase patient engagement, such as customizing diary content and reminders based on patient needs, using user-friendly interfaces, and incorporating social and gamification features [21], or integration with wearable devices, might also help improve adherence. Using personalized adaptive reinforcement learning as a core behavioral strategy, it may be possible to optimize intervention timing and minimize alert fatigue, ensuring more stable long-term user participation in the future [43]. In this study, patients expressed a desire to see immediate visual representations of daily symptom changes. Understanding the psychological factors (eg, motivation) and socioeconomic status behind patient adherence could be invaluable for designing more effective interventions.

Study Strengths

Our study introduces a significant innovation in GERD management through the development of a web-based e-diary designed for daily symptom assessment. The primary strength of this approach lies in its ability to provide real-time, prospective data collection, thereby fundamentally overcoming the limitations of traditional paper-based questionnaires and retrospective recall, which are prone to significant recall and ecological biases for patients with GERD [44]. Unlike conventional studies that often rely on symptom scores primarily as a measure of drug response, our e-diary integrates symptom monitoring directly into daily clinical practice. This shift allows for the capture of fine-grained, fluctuating symptom patterns over an extended period, providing a more accurate and comprehensive understanding of the patient's condition. Second, by minimizing recall bias, our e-diary ensures higher data entry quality and more efficient data handling compared to traditional methods. Third, it empowers patients to actively participate in their self-management by collecting health data autonomously, fostering self-reliance and improved awareness of their condition [45]. Fourth, with the application of an SMS reminder system and educational feedback provided, the adherence rate of patients could be maintained up to 8 weeks, especially for those symptomatic patients. Fifth, our study benefits from the e-diary's ability to separately capture daytime and nighttime GERD symptoms. This distinction is clinically important, as nocturnal reflux is characterized by impaired esophageal clearance and is associated with more aggressive disease, including a higher risk of severe complications such as esophagitis [46]. Moreover, nighttime symptoms substantially impair patients' health-related quality of life [36]. These granular, time-specific symptom data provide essential insights for developing personalized management strategies. Finally, the detailed, real-time symptom data facilitate enhanced patient-physician collaboration. Physicians can readily visualize symptom changes, understand the variability in symptoms, and work more effectively with patients to tailor treatment strategies [47]. This paves the way for truly personalized treatment plans in the future that can adapt to individual patient needs and daily life events, potentially incorporating dietary or other therapeutic adjustments. Ultimately, this approach moves beyond simple response assessment, enabling a proactive feedback loop that can lead to more informed and timely clinical decisions, fostering greater confidence in management for both clinicians and patients.

Study Limitations

Limitations do exist in the study. First, patients with GERD were enrolled from a single center and included only patients capable of operating an e-diary, potentially limiting the generalizability and overestimating adherence. Validation in multicenter or community-based cohorts should be conducted in the further studies. Second, days on which patients did not complete entries were recorded as symptom-free when calculating symptom frequency, which may lead to underestimation of the reported symptoms. Third, objective physiological parameters (eg, 24 h pH-impedance monitoring, reflux-symptom association probability, or treatment response) were not detected in this study, which would enhance the e-diary's clinical utility. Fourth, although SMS reminders improved the adherence, they might inadvertently increase psychological stress, symptom vigilance, or anxiety, which also may lead to worsening of GERD symptoms. This may account for part of the nonadherence observed in this study. Assessment of the Esophageal Hypervigilance and Anxiety Scale and other psychological measurements is warranted in subsequent studies to help balance engagement benefits against potential harm. Finally, we did not evaluate the satisfaction scores of patients with GERD and caring physicians. Further adjustments to this GERD e-diary by correcting the aforementioned limitations should be considered in future studies.

Conclusions

Our results demonstrate that system optimization can significantly enhance adherence in the newly developed GERD e-diary recording. Increased GERD symptom frequency was associated with adherence, although overall engagement declined gradually over 8 weeks. The development of this PRO-based GERD e-diary system can be a convenient tool for future application in clinical and research settings.

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The authors declare the use of generative AI in the writing process. According to the GAIDeT taxonomy (2025), the following tasks were delegated to GAI tools under full human supervision: summarizing text and translation. The GAI tool used was ChatGPT 4. Responsibility for the final manuscript lies entirely with the authors. All AI-generated text was reviewed or revised by the authors before submission. GAI tools are not listed as authors and do not bear responsibility for the final outcomes.

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Data Availability

The datasets generated or analyzed during this study are available from the corresponding author on reasonable request.

Authors' Contributions

Conceptualization: YCC, YPW, LFC, CLL, MLP, YHP, DWW, SLW
Data curation: YCC, SLW
Formal analysis: SLW
Funding acquisition: LFC, CLL, MLP, DWW
Investigation: YPW, CLL, YCC
Methodology: MLP, JHH
Project administration: CLL, MLP, YCC
Resources: YPW, CLL, MLP, LFC, YHP, DWW
Software: MLP, JHH, LFC
Supervision: CLL, LFC, YHP, MLP, DWW, SLW
Validation: YCC, CLL, YPW
Visualization Writing – original draft: YCC, YPW, CLL
Writing – review & editing: YCC, YPW, CLL, MLP, YHP, LFC, SLW
MLP and CLL are co-corresponding authors.

Conflicts of Interest

None declared.

Checklist 1

STROBE checklist.
[PDF File (Adobe File), 93 KB-Checklist 1]

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Abbreviations

e-diary: electronic diary
EQUATOR: Enhancing the Quality and Transparency of Health Research
GERD: gastroesophageal reflux disease
PRO: patient-reported outcome
STROBE: Strengthening the Reporting of Observational Studies in Epidemiology

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