

Article

Short-Term Outcomes of Elobixibat in Home-Care Patients with Chronic Constipation: A Multicenter, Prospective, Observational Study

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Abstract

The aim of this study was to evaluate short-term outcomes and safety of elobixibat in home-care patients with chronic constipation (CC) and explore the changes in caregiver burden related to bowel management. This multicenter prospective observational study evaluated bowel movement status, defecation-related symptoms, and caregiver burden in home-care patients diagnosed with CC who had hard stools classified as Bristol Stool Form Scale (BSFS) type 1 or 2. Elobixibat was administered to home-care patients once a day for 4 weeks before a meal. The primary endpoint was the proportion of patients with normal stools at week 2 in patients who were able to excrete independently. Secondary endpoints included the proportion of patient with normal stools at week 4, stool consistency, stool frequency, defecation-related symptoms at weeks 2 and 4, caregiver burden at week 4, concomitant laxative use during the study period, and adverse events. Analyses were based on available data at each assessment time point. The proportion of patient with normal stools at week 2 in patients who could excrete independently was 53% (8/15; 95% CI, 30–75%). Weekly defecation frequency significantly increased at week 4 ($n = 20$, $p = 0.02$, without multiplicity adjustment) and was associated with potential improvements in defecation-related symptoms (straining, abdominal bloating) and patient satisfaction. The most common adverse event was mild diarrhea (17%), with no new safety signals observed over 4 weeks. The caregiver questionnaire, evaluated in a limited subset of seven respondents, showed preliminary descriptive changes in physical, psychological, and social burdens. This uncontrolled, exploratory observational study suggests that elobixibat was associated with improvements in defecation-related outcomes in home-care patients with CC. However, these findings should be interpreted with caution due to the small sample size and potential confounding from concomitant laxative use. Caregiver burden findings were descriptive and hypothesis-generating and require confirmation in larger, controlled studies.



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1. Introduction

1.1. Aging Population and Chronic Constipation in Home Care Settings

Japan is one of the most rapidly aging countries in the world, with people aged 65 years and older accounting for 29% of the total population as of 2024 [1]. In response to this super-aged demographic structure, the Japanese government has promoted a community-based integrated care system in which home medical care plays a central role [2]. As the number of older adults receiving home care continues to increase, the management of chronic conditions in this setting has become an important clinical and societal issue. The prevalence of chronic constipation (CC) increases with age, and 57% of home-care patients in Japan experience constipation [3]. Hard stools require intense straining during defecation and cause pain, avoidance of defecation, and a decreased frequency of defecation, presumably contributing to physical and psychological burden [4].

1.2. Clinical Challenges and Caregiver Burden

The Bristol Stool Form Scale (BSFS) classifies stools into seven types based on their consistency. It is used to determine the severity of constipation. For this study, BSFS scores of 1 and 2 were grouped to indicate hard stools; scores of 3 to 5 were grouped together to indicate normal stools; and scores of 6 and 7 were grouped together to indicate soft stools [5]. A study in Japan reported that hard stools with a BSFS score of 1 or 2 not only decrease patient satisfaction but are also associated with the concomitant use of multiple laxatives and increased treatment costs [6]. In terms of patient satisfaction, a treatment that can stably produce normal stools (BSFS score 3 to 5) is strongly desired [5].

In Japan, approximately 90% of caregivers provide assistance with excretion in home-care setting [7], which has been identified as a major contributor to caregiver burden [8]. In addition to the distress experienced by patients themselves, constipation and other bowel-related problems, such as fecal impaction or diarrhea, often triggered by laxative use or manual disimpaction, have been shown to increase physical, psychological, and socioeconomic burdens on caregivers [8]. Moreover, recent clinical perspectives conceptualize chronic constipation in older adults not merely as an isolated gastrointestinal symptom, but as a systemic geriatric syndrome closely intertwined with frailty, polypharmacy, and functional decline [9]. This paradigm shift underscores the necessity for management strategies to evolve from simple symptomatic relief to comprehensive, individualized care that effectively mitigates the overall healthcare burden. Therefore, there is a need for a treatment that can improve stool consistency from hard to normal, rather than simply increasing defecation frequency, as this may benefit patient and reduce caregiver burden.

1.3. Role of Elobixibat and Study Objectives

Elobixibat, a medication used for CC, was launched in Japan in April 2018. Elobixibat inhibits bile acid transporters (IBAT/ASBT) and promotes bile acid influx into the large intestine, thereby promoting water secretion, colonic peristalsis, and defecation desire [10–14]. Phase III clinical studies and post-marketing surveillance have reported that elobixibat improves the frequency of spontaneous bowel movement and stool consistency, and has a good safety profile [15–17]. However, these studies did not exclusively evaluate home-care patients. Consequently, high-quality, real-world longitudinal data validating multidimensional management approaches for frail, home-dwelling older adults remains critically scarce. To fill this gap, this study prospectively investigated short-term outcomes and safety of elobixibat in home-care patients with CC and explored its effect on caregiver burden related to bowel management.

2. Methods

2.1. Study Design

This was a multicenter prospective observational study. We evaluated the short-term outcomes and safety of elobixibat at weeks 2 and 4 after the initiation of treatment in home-care patients diagnosed with CC at the Satsuki Home Clinic, Satsuki Home Clinic Kanuma, and Satsuki Home Clinic Mashiko. We also surveyed caregiver burden related to bowel management and observed changes before and after treatment with elobixibat.

2.2. Participants

The study period was from the date of the ethical review approval (19 January 2024) to 30 November 2024. Eligible participants were home-care patients aged 20 years or older at the time of consent, who were diagnosed with CC by a physician, were newly prescribed elobixibat (10 mg once a day before meals), had hard stools of BSFS 1 or 2 over the previous week, and could provide written consent to participate in the study. Eligible participants were classified into two groups: those who could excrete independently in the toilet and those who were bedridden and unable to excrete independently in the toilet.

Patients with a history of hypersensitivity to elobixibat, those who were confirmed or suspected to have intestinal obstruction due to tumors or hernias, those who were suspected to have constipation due to organic diseases, those who had been taking elobixibat within the past four weeks, and those with serious renal, hepatic, or heart diseases were excluded. Furthermore, patients who were judged by a physician to be ineligible to participate in the study for reasons such as threats to the safety of the patient or difficulty in complying with the study protocol were excluded. Caregivers were required to be 20 years of age or older at the time of consent, live with the patient, assist with bowel management care, and provide written consent to participate in the study.

2.3. Endpoints

The primary endpoint was the proportion of patients with normal stools at week 2 of elobixibat administration in patients who could use the toilet independently. The target sample size of 15 patients was determined based on the realistic number of independently toileting home-care patients who could be enrolled at the participating clinics. This sample size was not intended for confirmatory hypothesis testing, and the study prioritized exploratory presentation of real-world clinical data rather than estimation precision.

Secondary endpoints included: the proportion of patient with normal stools at week 4 of elobixibat treatment in patients who could excrete independently, the proportion of patient with normal stools at weeks 2 and 4 in patients who were bedridden and unable to excrete independently, the proportion of patient with normal stools at weeks 2 and 4 in all patients, stool consistency, weekly defecation frequency, straining during defecation, abdominal bloating, and patient satisfaction with bowel movements at weeks 2 and 4 compared with those before treatment. The use of concomitant constipation medications was also investigated. In addition, changes in the caregiver burden related to bowel management before treatment and at week 4 were evaluated.

Safety endpoints included the type and incidence of adverse events, adverse drug reactions, and the discontinuation rate.

2.4. Data Sources and Measurement

Interviews with the participants were conducted before treatment and at weeks 2 and 4, while interviews with caregivers were conducted before treatment and at week 4. At each interview, the research staff requested the participants and caregivers to complete

the questionnaire. If a participant had difficulty completing the form independently, the research staff conducted an interview and completed the form based on their responses.

The questionnaire for research participants was developed based on items used in the post-marketing surveillance of elobixibat [16,17]. It included questions on stool consistency based on the BSFS (1: hard; 2: normal; 3: soft), weekly defecation frequency, straining during defecation (1: never; 2: rarely; 3: occasionally; 4: frequently; 5: always), abdominal bloating using the same 5-point scale, and patient satisfaction (1: satisfaction; 2: slight satisfaction; 3: slight dissatisfaction; 4: dissatisfaction). For straining, abdominal bloating, and patient satisfaction, lower scores indicated more favorable outcomes.

The questionnaire for caregivers was a study-specific instrument adapted from a previously published Japanese study [8]. It assessed physical, psychological, social, and economic burdens related to bowel management using a 4-point scale (very burdensome, somewhat burdensome, not very burdensome, and not burdensome). This questionnaire was not formally validated or pilot-tested; therefore, the caregiver burden results were interpreted as descriptive and exploratory.

2.5. Ethical Considerations

This study was conducted in accordance with the Declaration of Helsinki (modified at the WMA General Assembly, Fortaleza, Brazil in 2013) and the Ethical Guidelines for Medical and Biological Research Involving Human Subjects (Ministry of Education, Culture, Sports, Science and Technology; Ministry of Health, Labour and Welfare; and Ministry of Economy, Trade and Industry Notification No. 1, March 2021, partially amended in March 2023). After obtaining approval from the Ethics Review Committee of ITO Yoyogi Mental Clinic, the study was registered with the University Hospital Medical Information Network (UMIN) (UMIN 000053633).

2.6. Statistical Analysis

All analyses were performed using the full analysis set (FAS), which comprised all enrolled patients, excluding those for whom no data other than registration information were collected after enrollment. In accordance with the prespecified statistical analysis plan, analyses were conducted using the available data for each endpoint and time point, without imputation for missing data; therefore, the number of patients included in the analyses varied across endpoints and time points. No sensitivity analysis for missing data was performed. Categorical variables were summarized as numbers and percentages, and continuous and ordinal variables were summarized as medians and interquartile ranges (IQR). For the primary endpoint, the proportion of patients with normal stools at week 2 and its two-sided 95% confidence interval were calculated using the Wilson score method. Changes from baseline in the secondary endpoints were assessed using the Wilcoxon signed-rank test, in accordance with the prespecified statistical analysis plan. No adjustment for multiplicity was performed; therefore, all *p*-values were interpreted as exploratory and descriptive. SAS Release 9.4 (SAS Institute Inc., Cary, NC, USA) was used for statistical analyses.

3. Results

3.1. Participant Background

A participant flow diagram is shown in Figure 1, and the participants' backgrounds are shown in Table 1. Twenty-three home-care patients with CC were enrolled in this study. Among them, 17 patients were able to excrete independently, and 6 patients were bedridden and unable to excrete independently. The mean age of the 23 patients was 84.9 years (range: 68–94 years), and 65% were male. Complications were observed in all patients; the most

common were hypertension (65%), cardiovascular disease (57%), and mental disorders, including dementia (52%). Eighty-three percent of the patients had a history of constipation treatment within one month prior to treatment. The most commonly used drugs were magnesium oxide (78%), stimulant laxatives (35%), and Lubiprostone (17%). The nursing care level was level 1 or higher for all patients, and the most common level was level 3 (30%). The duration of constipation was 6 months or more in all patients, 39% for less than 1 year, 22% for less than 5 years, 22% for less than 10 years, and 17% for more than 10 years.

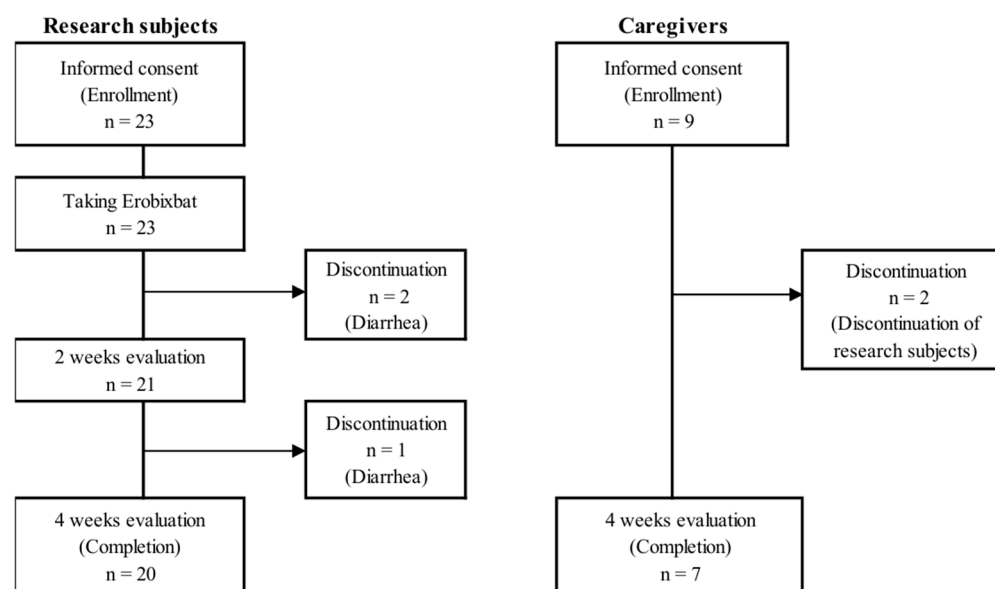


Figure 1. Participant flow diagram.

Table 1. Baseline characteristics of patients.

Number of patients		23
Age (years)	Mean value	84.9
	Standard deviation	7.7
Sex	Male	15 (65%)
	Female	8 (35%)
Complications	Absent	0 (0%)
	Present	23 (100%)
Complications (with duplicates)	Cardiovascular disease	13 (57%)
	Cerebrovascular disease	5 (22%)
	Mental disorder (including dementia)	12 (52%)
	Respiratory diseases	5 (22%)
	Hypertension	15 (65%)
	Dyslipidemia	9 (39%)
	Diabetes mellitus	4 (17%)
	Others	19 (83%)
Pre-treatment (1 month): Laxative/Enema/Manual disimpaction	Without	4 (17%)
	With	19 (83%)
Types of pre-treatment drugs (with duplicates)		
Stimulant laxatives		8 (35%)
Osmotic laxative	Magnesium oxide (MgO)	18 (78%)
Prosecretory agents	Lubiprostone	4 (17%)
Number of enema uses (within 1 month prior to treatment initiation)	Number of patients	2
Number of manual disimpaction procedures (within 1 month prior to treatment initiation)	Number of patients	1

Table 1. *Cont.*

Care level at the time of enrollment (under Japan's Long-Term Care Insurance system)	Care Level 1	3 (13%)
	Care Level 2	4 (17%)
	Care Level 3	7 (30%)
	Care Level 4	4 (17%)
	Care Level 5	5 (22%)
Duration of constipation	≥6 months and <1 year	9 (39%)
	≥1 year and <5 years	5 (22%)
	≥5 years and <10 years	5 (22%)
	≥10 years	4 (17%)

Percentage of the total represents the ratio (%) to the analyzed population.

3.2. Stool Consistency

Among the 17 participants who could excrete independently, stool consistency data were available for 15; two participants were excluded from the analysis because stool consistency could not be assessed. Reductions in sample size at subsequent time points were primarily due to treatment discontinuation. No missing data were imputed, and analyses were conducted using available-case analysis. Among patients who could excrete independently, 53% (8/15; 95% CI, 30–75%) had normal stools at week 2 (Supplementary Material File Table S1). All 21 patients whose stool consistency could be evaluated before treatment had hard stools at baseline (21/21, 100%). At week 2 ($n = 20$), the number of patients with hard stools decreased to seven (7/20, 35%); ten patients (10/20, 50%) had normal stools and three patients (3/20, 15%) had soft stools. At week 4 ($n = 19$), the number of patients with normal stools increased to 12 (12/19, 63%), while five patients (5/19, 26%) had hard stools and two patients (2/19, 11%) had soft stools (Supplementary Material File Table S1).

3.3. Defecation Frequency

For patient outcomes other than stool consistency, analyses were conducted using available-case analysis. The mean weekly defecation frequency significantly increased from 2.4 times/week ($n = 23$) before treatment to 3.4 times/week ($n = 21$, $p = 0.04$) at weeks 2 and 3.5 times/week ($n = 20$, $p = 0.02$) at week 4 (Table 2).

Table 2. Comparison of defecation-related symptoms and patient satisfaction before treatment with elobixibat and at weeks 2 and 4.

(A) Patients Who Can Excrete Independently					
Endpoints	Evaluation Period	<i>n</i>	Statistics		
			Median	IQR	<i>p</i> -Value *4
Stool consistency (Score: 1–3) *1	Before treatment	15	1.0	1.0–1.0	$p = 0.002$ $p < 0.001$
	Week 2	15	2.0	1.0–2.0	
	Week 4	15	2.0	2.0–2.0	
Defecation frequency per week	Before treatment	17	2.0	1.0–4.0	$p = 0.25$ $p = 0.05$
	Week 2	16	2.5	1.5–4.5	
	Week 4	16	3.0	2.5–5.0	
Straining during defecation (Score: 1–5) *2	Before treatment	17	3.0	2.0–4.0	$p = 0.43$ $p = 0.03$
	Week 2	16	2.5	2.0–3.5	
	Week 4	16	2.0	1.0–3.0	
Abdominal bloating (Score: 1–5) *2	Before treatment	17	2.0	2.0–4.0	$p < 0.001$ $p = 0.14$
	Week 2	16	1.0	1.0–2.5	
	Week 4	16	2.0	1.0–3.0	
Patient satisfaction (Score: 1–4) *3	Before treatment	17	3.0	3.0–3.0	$p = 0.20$ $p = 0.03$
	Week 2	16	2.5	1.5–3.0	
	Week 4	16	2.0	1.0–3.0	

Table 2. Cont.

(B) All Patients					
Endpoints	Evaluation Period	n	Statistics		
			Median	IQR	p-Value ^{*4}
Stool consistency (Score: 1–3) ^{*1}	Before treatment	21	1.0	1.0–1.0	$p < 0.001$ $p < 0.001$
	Week 2	20	2.0	1.0–2.0	
	Week 4	19	2.0	1.0–2.0	
Defecation frequency per week	Before treatment	23	2.0	1.0–4.0	$p = 0.04$ $p = 0.02$
	Week 2	21	3.0	2.0–5.0	
	Week 4	20	3.0	2.0–5.0	
Straining during defecation (Score: 1–5) ^{*2}	Before treatment	23	3.0	2.0–4.0	$p = 0.36$ $p = 0.06$
	Week 2	21	2.0	2.0–4.0	
	Week 4	20	2.0	1.0–3.0	
Abdominal bloating (Score: 1–5) ^{*2}	Before treatment	23	3.0	2.0–4.0	$p < 0.001$ $p = 0.03$
	Week 2	21	1.0	1.0–2.0	
	Week 4	20	2.0	1.0–3.0	
Patient satisfaction (Score: 1–4) ^{*3}	Before treatment	23	3.0	3.0–3.0	$p = 0.09$ $p = 0.007$
	Week 2	21	3.0	2.0–3.0	
	Week 4	20	2.0	1.5–2.0	

^{*1} Stool consistency: 1, hard; 2, normal; 3, soft. Higher scores indicate softer stools. ^{*2} Straining during defecation and abdominal bloating: 1, never; 2, rarely; 3, occasionally; 4, frequently; 5, always. Higher scores indicate greater frequency or severity of symptoms. ^{*3} Patient satisfaction: 1, satisfied; 2, slightly satisfied; 3, slightly dissatisfied; 4, dissatisfied. Higher scores indicate lower satisfaction. ^{*4} Statistical analysis: *p*-values were calculated using the Wilcoxon signed-rank test. Sample size: For stool consistency, two patients were excluded from the analysis because stool consistency could not be assessed. For all other outcomes, reductions in sample size over time were primarily due to treatment discontinuation.

3.4. Other Defecation-Related Symptoms

The mean score of abdominal bloating before treatment was 2.7 ± 1.3 , which decreased to 1.7 ± 1.0 at week 2, showing a statistically significant change ($p < 0.001$). At week 4, the score was 2.0 ± 1.0 , which was significantly lower than before treatment ($p = 0.03$) (Table 2). The mean satisfaction score decreased from 3.0 ± 0.6 before treatment to 2.5 ± 1.1 at week 2 and 2.2 ± 0.9 at week 4 ($p = 0.007$) (Table 2); lower scores indicate improved satisfaction under this scoring system.

3.5. Usage Status of Concomitant Laxatives

Stimulant laxatives were used by eight patients at enrollment, and nine patients at weeks 2 and 4. The use of osmotic laxatives decreased slightly from 18 patients at enrollment to 16 patients at week 2 and 15 patients at week 4. Nevertheless, there was no clear change in the trend of concomitant medication use overall. The use of linaclotide, traditional Chinese medicine, and probiotics was not observed during the study period, and Lubiprostone was regularly used by four patients.

Therefore, the observed changes in this study should be interpreted as occurring following the initiation of elobixibat in a real-world treatment context, rather than as effects that can be attributed to elobixibat alone.

3.6. Assessment of Caregiver Burden Related to Bowel Management

Caregivers of home-care patients were given questionnaires with four categories using a 4-point scale to assess the subjective burden related to bowel management. Table 3 shows the age and sex of the caregivers who responded to the questionnaire and the characteristics of the patients for whom the caregivers provided care. Of the nine caregivers registered in the study, seven were included in the analysis as they provided complete questionnaire responses both at registration and during the observation period. Two caregivers were excluded because the patients discontinued their participation, resulting in incomplete

data. Most of the caregivers were older female adults who did not receive support from other caregivers. Patients who received care were mainly older male adults.

Table 3. Background of caregivers.

Caregivers		
Number of caregivers		9
Age (years)	Mean value	72.2
	Standard deviation	11.6
Sex	Male	1 (11%)
	Female	8 (89%)
Care recipients		
Number of care recipients		9
Age (years)	Mean value	83.4
	Standard deviation	9.6
Sex	Male	8 (89%)
	Female	1 (11%)
Independent in toileting	Independent	5 (56%)
	Dependent	4 (44%)
Availability of other caregivers	No	9 (100%)
	Yes	0 (0%)

Percentages for total figures represent the ratio (%) to all caregivers.

Regarding the overall burden of daily life, the proportion of caregivers who responded “somewhat burdensome” decreased from 71% before treatment to 14% at week 4, and the proportion of respondents who responded “not very burdensome” increased from 29% to 71%. Regarding physical burden, the proportion of respondents who responded “not very burdensome” increased from 14% before treatment to 43% at week 4, and the proportion of respondents who responded “very burdensome” decreased from 14% before treatment to 0% at week 4. Regarding psychological burden, the proportion of respondents who responded “somewhat burdensome” decreased from 71% to 29%, and the proportion of respondents who responded “not very burdensome” increased from 0% to 57%. Regarding social and economic burden, the proportion of respondents who responded “not burdensome” increased from 29% to 43%. At week 4, several domains shifted descriptively toward lower burden; however, for the item “degree of burden related to bowel management in daily life”, one caregiver rated it as “very burdensome” at week 4 whereas none did at baseline (Table 4).

Table 4. Caregiver burden related to bowel management before treatment with elobixibat and at week 4.

Questions for Caregivers	Evaluation Period	n	Scale			
			Very Burdensome	Somewhat Burdensome	Not Very Burdensome	Not Burdensome
Degree of burden related to bowel management in daily life	Before treatment	7	0 (0%)	5 (71%)	2 (29%)	0 (0%)
	Week 4	7	1 (14%)	1 (14%)	5 (71%)	0 (0%)
Physical burden related to bowel management	Before treatment	7	1 (14%)	2 (29%)	1 (14%)	3 (43%)
	Week 4	7	0 (0%)	1 (14%)	3 (43%)	3 (43%)
Psychological burden related to bowel management	Before treatment	7	0 (0%)	5 (71%)	0 (0%)	2 (29%)
	Week 4	7	0 (0%)	2 (29%)	4 (57%)	1 (14%)
Social and economic burden related to bowel management	Before treatment	7	0 (0%)	3 (43%)	2 (29%)	2 (29%)
	Week 4	7	0 (0%)	1 (14%)	3 (43%)	3 (43%)

Among patients with caregivers, the proportion of patients who had normal stools at week 4 was 57% (4/7; 95% CI: 25–84%), consistent with the FAS (Supplementary Material File Table S1).

3.7. Safety

Adverse events were evaluated in all 23 patients treated with elobixibat. Adverse events were observed in 17% (four patients) of the patients, all of whom were classified as having gastrointestinal disorders (diarrhea). Thirteen percent (three patients) discontinued elobixibat, all of whom had mild symptoms and recovered. No serious adverse events were observed.

4. Discussion

4.1. Significance of the Study in the Home Care Setting

This is the first prospective observational study to evaluate the efficacy and safety of elobixibat in home-care patients with CC and investigate caregiver burden related to bowel management. Phase III clinical trials and post-marketing surveillance conducted to date have mainly included patients who can be seen as outpatients, and the data was not specific to home-care patients [15–17]. Therefore, this study intended to provide new insights relevant to the field of home healthcare for patients and caregivers under daily home care in a real-world setting. However, this study should be interpreted as a small, uncontrolled, short-term exploratory observational analysis conducted in a real-world home-care setting.

4.2. Efficacy and Safety of Elobixibat

In this study, the primary endpoint was stool consistency at week 2 in patients who were able to excrete independently. The proportion of patients with “normal stools” improved from zero before treatment to 53% at week 2, with more than half of them showing improvement. Of the 15 patients, 10 had previously been treated with other constipation medications without improvement in stool consistency. Nevertheless, even in these treatment-refractory cases, elobixibat use was associated with a trend toward normalization of the stool form. Additionally, the observation that a higher proportion of patients achieved normal stool as early as week 2 is consistent with previous phase III clinical trials and post-marketing surveillance, which reported that the efficacy of elobixibat was notable at week 2 after initiation of administration [15–17]. Furthermore, this study observed participants until week 4, and the pattern of stool consistency at week 2 was largely maintained at week 4. In sum, changes in stool consistency were observed from the early stage of administration and persisted for at least 4 weeks. A report stated that stool consistency and frequency of bowel movements are related to the quality of life (QOL) of patients with CC and that normal stool (BSFS type 4) is particularly important for improving the QOL of constipated patients [18]. Therefore, maintaining normal bowel movements is expected to benefit patient well-being, although QOL was not directly evaluated in this study.

4.3. Impact on Defecation-Related Symptoms and Patient Satisfaction

At the secondary endpoints, several defecation-related symptoms, such as the frequency of bowel movements, straining, abdominal bloating, and patient satisfaction, showed an improvement trend in both the quantity and quality of bowel movements.

The frequency of bowel movements improved significantly, although it was slightly lower than previously reported [15–17]. This may be due to factors specific to home-care patients, such as diet and exercise, and generally, daily bowel movements are not always

necessary in such cases [19]. In real-world home care settings, if the patient has bowel movements approximately three times a week, there are no health management issues. Therefore, the frequency of bowel movements (week 2: 3.4/week, week 4: 3.5/week) confirmed in this study is meaningful for home-care patients. Importantly, the observed changes were accompanied by favorable changes in stool consistency and patient-reported symptoms. Therefore, the clinical relevance of the findings may be better reflected by the overall pattern of changes across multiple constipation-related outcomes rather than by bowel movement frequency alone.

There was a significant improvement in the abdominal bloating score at week 2. This is a valuable finding because many patients with CC are dissatisfied with abdominal bloating [20]. In addition, since straining can temporarily elevate blood pressure and increase the risk of cardiovascular events, reducing the degree of straining is clinically significant, particularly for patients with cardiovascular disease. In older patients, especially those with cardiovascular disease, it is important to reduce straining from the viewpoint of event reduction [21] and elobixibat can reduce straining in patients with heart failure [22]. In this study, some patients also had concomitant cardiovascular disease despite the small sample size. Although no statistically significant difference was observed, the increase in the number of participants who reported experiencing “no” straining may be of potential clinical relevance and warrants further investigation. In any case, “abdominal bloating,” “infrequent bowel movements,” and “hard stool” are common and bothersome symptoms in patients with constipation [20], and the observed tendency toward symptom relief might have contributed to patient satisfaction.

Additionally, in this study, there was no clear change in the use of constipation drugs such as stimulant laxatives and Lubiprostone before and after elobixibat treatment, and almost all patients remained on a continuous prescription. It could be suggested that elobixibat represents a possible approach for patients who do not respond adequately to the full dose of magnesium oxide or for those who cannot increase their magnesium oxide dosage because of the risk of hypermagnesemia associated with the age-related decline in renal function. However, methods for reducing or switching the dose of concomitant constipation medications have not yet been established, and this remains an issue to be addressed.

4.4. Safety Profile and Concomitant Medication Management

In older patients, it is necessary to pay attention to dehydration and falls associated with diarrhea. In this study, gastrointestinal disorders (diarrhea) were observed in 4 (17%) of the 23 patients, and 3 (13%) discontinued elobixibat, but there were no serious adverse events. However, given the short follow-up and small sample size, these data should be interpreted as preliminary; careful monitoring remains important, especially in older adults.

Based on these results, elobixibat, which has a novel mechanism of action distinct from conventional treatments, was associated with improvements in stool-related outcomes over 4 weeks in this home-care cohort, and no new safety signals were observed. However, given the uncontrolled design, short follow-up, and unchanged concomitant laxative use, these findings should not be interpreted as evidence of efficacy or practical superiority, but rather as exploratory real-world signals suggesting possible benefit. Although the sample size was extremely small and no formal subgroup analyses were performed, descriptive summaries of stool consistency stratified by concomitant laxative use and other baseline characteristics are presented in Supplementary Material File Table S2. Data from longer-term and controlled studies are needed to better characterize effectiveness and safety in this population.

4.5. Caregiver Burden Related to Bowel Management

In a home care environment, bowel management is a significant challenge not only for the patients themselves but also for their family members who provide care. Particularly, in cases where constipation is chronic and daily interventions, such as fecal disimpaction and enemas, are required, caregivers face physical fatigue, mental stress, and social burden [8]. In this study, caregiver-reported burden was evaluated subjectively and descriptively; some domains appeared to shift toward lower burden after the introduction of elobixibat, but the findings are hypothesis-generating.

As mentioned earlier, the number of respondents in this study was limited, and statistical generalizations require caution. A validated caregiver burden instrument was not used because the primary aim of this exploratory study was to capture bowel-management-specific burden in a real-world home-care setting. Therefore, a study-specific questionnaire adapted from a previously published Japanese survey was used. Nevertheless, the lack of formal validation limits interpretability and comparability with other studies. It would seem that some caregiver responses appeared to shift toward a lower burden, but these findings are preliminary and require confirmation using validated caregiver-reported outcome measures. Given that many caregivers are older adults, such a reduction in burden is an important factor directly related to the sustainability of nursing care itself [8]. These findings suggest that elobixibat may have the potential to support both patients and caregivers, although further studies are needed.

Although these findings remain exploratory at present, focusing on the outcomes of not only patients, but also caregivers in the evaluation of constipation drugs will become increasingly important for future home healthcare. This qualitative evaluation of the burden of bowel management in family caregivers is positioned as a new perspective in real-world settings, and a more systematic investigation is required.

4.6. Limitations

This study had several limitations. First, as this was an exploratory study, the sample size was small, limiting the statistical reliability of the results. Furthermore, although explanatory analyses were originally planned for pre-specified subgroups (e.g., concomitant medication use, care level, and toileting independence), they could not be conducted because of insufficient statistical precision to reliably estimate the results from the limited sample size. Consequently, no formal adjustments were performed for confounding factors. To facilitate interpretation of potential confounding effects, descriptive summaries stratified by selected baseline characteristics, including age, sex, concomitant laxative use, and care level, are provided in the Supplementary Material File Table S2. However, these subgroup summaries should be interpreted cautiously because the study was not powered for subgroup comparisons. Second, this study used a non-controlled design. Therefore, it is difficult to determine whether the observed improvements were solely due to the study drug or were influenced by the natural clinical course or concurrent interventions. Consequently, the efficacy of elobixibat may have been over- or underestimated, and the results should be interpreted with caution. Third, the BSFS score, which is a relatively objective index, was used to evaluate the stool consistency. However, other evaluation items used questionnaires with non-standardized scales that could be affected by subjective errors and memory bias. Therefore, the possibility of an overestimation cannot be ruled out. Fourth, the follow-up period was short (4 weeks), which limits the assessment of longer-term effectiveness, safety, and caregiver outcomes in a frail home-care population. Fifth, in addition to the non-controlled design, concomitant laxatives largely remained in use during follow-up and may have confounded the observed changes; thus, improvements cannot be attributed to elobixibat alone. Additionally, due to the small sample

size, statistical adjustments (e.g., multivariate analysis) to account for concomitant medications as confounding factors were not feasible. Nevertheless, this pragmatic design reflects the real-world clinical status of home care patients. Sixth, the caregiver burden questionnaire was adapted from prior work [8] but has not been validated, and its content validity and reproducibility are uncertain. Additionally, the caregiver analysis was based on a small subset of caregivers, further limiting the robustness and generalizability of the caregiver-related findings. Complete responses were obtained from only seven caregivers, so we cannot definitively conclude that caregiver burden decreased. These findings should be regarded strictly as preliminary and as a basis for future studies. Seventh, although multiple statistical tests were performed, no multiplicity adjustment was applied. Since this study was designed as an exploratory analysis to generate hypotheses for future research rather than to confirm definitive efficacy, adjustments for multiple comparisons were not made, and the results should be interpreted with caution. Eighth, in the context of missing data, an available-case analysis was conducted, limited to the completed data points. This approach is an inherent limitation of this small-scale study, and care should be taken when interpreting the overall outcomes. Finally, data were derived from only three clinics, which may limit generalizability to broader home-care populations. Accordingly, all findings should be interpreted as exploratory and hypothesis-generating.

5. Conclusions

Although the efficacy and safety of elobixibat have been reported in phase III studies and post-marketing surveillance, evidence in home-care patients with CC remains limited. In this uncontrolled, exploratory prospective observational study, elobixibat use was associated with preliminary signals of improvement in stool-related outcomes. However, these findings should be interpreted with caution given the small sample size, the potential confounding effects of concomitant laxatives, and lack of a control group. Caregiver burden findings, based on a small subset of caregivers, were descriptive and hypothesis-generating. Further studies involving larger cohorts are required to evaluate these preliminary observations. Additional studies focusing specifically on the long-term impact on caregiver burden are required to clarify the clinical utility of elobixibat in home medical care.

Supplementary Materials: The following supporting information can be downloaded at: <https://www.mdpi.com/article/10.3390/jgg74030023/s1>, Supplementary Material File Table S1: Breakdown of defecation-related symptoms before treatment with elobixibat and at weeks 2 and 4. Supplementary Material File Table S2: Distribution of stool consistency and proportion of normal stools according to baseline characteristics before treatment with elobixibat and at weeks 2 and 4.

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Institutional Review Board Statement: This study was conducted in accordance with the Declaration of Helsinki (modified at the WMA General Assembly, Fortaleza, Brazil in 2013) and the Ethical Guidelines for Medical and Biological Research Involving Human Subjects (Ministry of Education, Culture, Sports, Science and Technology; Ministry of Health, Labour and Welfare; and Ministry of Economy, Trade and Industry Notification No. 1, March 2021, partially amended in March 2023). After obtaining approval from the Ethics Review Committee of ITO Yoyogi Mental Clinic (RKK980-322 on 19 January 2024), the study was registered with the University Hospital Medical Information Network (UMIN) (UMIN 000053633).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are only available on request from the corresponding author due to patient privacy and ethical restrictions.

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Abbreviations

The following abbreviations are used in this manuscript:

BSFS	Bristol Stool Form Scale
CC	Chronic constipation
CI	Confidence Interval
FAS	Full Analysis Set
UMIN	University Hospital Medical Information Network

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