Drugs - Real World Outcomes
https://doi.org/10.1007/s40801-024-00444-z

ORIGINAL RESEARCH ARTICLE

Real World Evidence of User Experience with Microenemas for Relief of Constipation

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Accepted: 20 June 2024

Abstract

Background Constipation is a commonly reported gastrointestinal complaint. Research on this widespread condition focuses mainly on clinical trials for chronic constipation with less emphasis on patient experience and nonchronic situations. Sufferers report that constipation interferes with daily activities and quality of life. It is likely that this is common among all sufferers of constipation, regardless of how often the condition is experienced.

Objective This work explored attitudes and perceptions of people who experience occasional constipation and self-treat with over the counter products, particularly Microlax® microenemas.

Methods In this retrospective study, real-world data were collected from 1635 respondents from France and Russia who experienced occasional constipation. Participants completed a questionnaire about their experiences with occasional (not chronic) constipation and perceptions of over the counter treatments of oral laxatives, suppositories, and Microlax microenemas. Questions focused on comfort, quality of life, ease of use, and reliability of these treatments. Participants had used the microenema for treatment of occasional constipation within 3 months of study participation. Occasional constipation was based on the Rome IV diagnostic criteria for adults and babies.

Data were analyzed across the total population of all groups, then by subgroup. Success criteria were defined as of at least 70% agreement with the statements scoring ≥ 7 on the scale of 0–10. The proportion of respondents agreeing with the individual statements was calculated using the denominator for the total sample within each group.

Results This study shows that experiencing even occasional bouts of constipation negatively affect quality of life and well-being. Participants (women aged 25–54 years, older men, and women aged 60–80 years) reported that it severely limited daily life and activities and caused negative emotions and embarrassment. Pregnant women and mothers with babies showed great concern that constipation indicated a serious and painful condition and was bad for their babies. Participants agreed that using Microlax microenema provided greater ease of use, comfort, reliability, and safety than oral laxatives and rectal suppositories.

Conclusions Sufferers of occasional constipation report that these bouts interfere with their daily lives and reduce quality of life, similar to what is reported for those with chronic constipation based on existing literature. The microenema, Microlax, showed benefits in the relief of occasional constipation compared with oral laxatives and rectal suppositories. Trepidation about using the microenema, experienced before using it, was greatly reduced after the first and subsequent uses. Microlax microenema enabled users to regain the feeling of control and provided positive impacts on quality of life and well-being.

1 Introduction

Constipation is one of the most commonly reported gastrointestinal complaints worldwide, with chronic constipation affecting up to 27% of the global population [1]. Nearly all people will experience occasional bouts of constipation during their lives, with a higher prevalence among women and older adults [2, 3]. The first line of defense is generally making diet and lifestyle changes, such as increasing exercise and fiber and water intake. In some cultures, home remedies may recommend specific foods [4] or postures [5] to aid in bowel evacuation. Additionally, patients self-treat with or are advised by their healthcare provider to use over the counter (OTC) options such as laxatives, taken orally, and suppositories and microenemas, delivered rectally. A microenema is a smaller version of a typical enema delivered by the

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Published online: 08 September 2024

Key Points

Treating occasional constipation with a rectally delivered microenema provides appreciable benefits for the user, such as reliability of relief, ease of use, and comfort, which may be superior to those found with the use of oral laxatives or rectal suppositories.

Occasional constipation is experienced by nearly all people. The results of this study show that people with occasional constipation experience concerns and negative quality of life impact. This is in line with published scientific literature on patients with chronic constipation.

These results equip healthcare practitioners and consumers with information about quality of life issues in the nonchronic constipation population and Microlax microenema as a favorable option to manage occasional constipation.

user via a squeeze tube filled with a liquid formulation. Prescription medications are also available, primarily for chronic situations.

Much of the research on this widespread condition focuses on controlled clinical trials on constipation that is chronic or caused by secondary factors. There is less emphasis on the patient experience and those with nonchronic episodes. However, it is clear that constipation can be an uncomfortable and embarrassing topic. Sufferers of constipation report that it can interfere with daily activities, quality of life (QoL), and emotional well-being [6] and create feelings of shame and isolation [7]. It is likely that these experiences, particularly around QoL issues, are common among all sufferers of constipation, regardless of how often the condition is experienced.

To understand the attitudes and experiences of those with occasional constipation who treated themselves at home, this research gathered real world data (RWD) about their views and actions following a recent incident of constipation. Real world research gathers information from people's actual experiences with products and healthcare interventions through the use of observational data and user opinion.

There is increasing recognition that real world evidence (RWE) can add value to assessments of users' experiences. Various regulatory bodies, such the Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the Medicines and Healthcare Products Regulatory Agency (MHRA), have developed guidelines for the use of RWE to demonstrate product efficacy or safety [8–10]. While the focus has been mostly on prescription pharmaceutical products, there are clear examples of using RWE to show benefits from using consumer healthcare products and devices [11–13]. In the United Kingdom, the Proprietary Association for Great Britain (PAGB) recently developed guidance for the design and application of real world research specifically to consumer healthcare products [14]. Following these guidelines, this research aims to study the real world experiences and attitudes in those with occasional constipation and their use of a specific treatment to provide relief.

2 Objective

The purpose of this work was to explore the attitudes and perceptions of people who experience occasional constipation and self-treat with over the counter healthcare products, particularly Microlax® microenemas.

2.1 Methods

A total of 1635 respondents participated in this retrospective study in which they completed online questionnaires related to comfort, quality of life, ease of use, and reliability after having purchased and used a microenema[1] for treatment of constipation within the previous 3 months of enrollment into the study. Respondents were recruited from France and Russia through social media channels, relevant websites and consumer research panels. Occasional constipation was based on the Rome IV diagnostic criteria for adults and babies [15]. To be eligible, adult subjects self-reported having occasional constipation, meaning they experienced at least two of the following symptoms no more than one to three times per month for no more than the last three months: straining when passing a stool; passing a stool that is lumpy or hard; feeling that bowels are not fully emptied; sensation of the rectal blockage; need to use manual actions to remove stools; less than three bowel movements per week. Additional inclusion criteria were the use of oral laxatives, suppositories or Microlax micro-enemas as their preferred OTC treatment for constipation; had used the micro-enema more than once and had purchased and used it within three months of study participation. In the Russia cohort, participants were users of at least both an oral laxative and Microlax. In the France cohort, due to recruiting difficulties, participants were users of Microlax microenema and either oral laxatives or suppositories. All participants demonstrated the ability to complete the online questionnaire and to provide informed consent.

[1] Microlax® rectal solution microenema, Kenvue

Table 1 Study demographics

Group	*N* (%)—Russia	*N* (%)—France
Females, 25–54 years	265 (23.7)	280 (54.2)
Pregnant females, ≥ 25 years	261 (23.3)	Not applicable
Mothers with babies < 3 years old	260 (23.3)	Not applicable
Males and females, 60–80 years	332 (29.7)	237 (45.8)
Total	1118 (100)	517 (100)

Exclusion criteria were the conditions of chronic constipation, defined as infrequent bowel movement or difficulty passing stools lasting for several weeks or longer, inflammatory bowel disease, Crohn's disease, bowel cancer, or pregnancy or breastfeeding (except for pregnant cohort in Russia). The study also used standard criteria that excluded any participants who engaged in a similar study in the previous 1 month or who had employment in the past 6 months in the pharmaceutical or consumer health industries, market research, advertising, or media employment.

For the pediatric group (Russia only), the parent/care giver must have reported observing occasional constipation in their child, with at least two of the following symptoms in their child: two or fewer bowel movements per week, history of incomplete emptying of bowels, history of painful or hard bowel movements, history of large stools.

The study was conducted in accordance with ICH Good Clinical Practice (GCP), all applicable subject privacy requirements [including European General Data Protection Regulation (GDPR)] and the guiding principles of the current version of the Declaration of Helsinki. In addition, approval to conduct the study was pursued with independent ethics committees in the respective countries; however, it was deemed to be unnecessary for this type of research. Respondents received a minimal incentive payment for their time in completing the questionnaire. The incentive complied with the industry-accepted guideline from the European Society for Opinion and Market Research (ESOMAR) [16].

Table 1 depicts study demographics.

Respondents were presented with a series of statements about perceptions and experiences of constipation and its impact on quality of life; experiences and perceptions of oral laxatives and suppositories; and comfort, quality of life, ease of use, and reliability/regularity about the microenema. Respondents provided input on each statement using a scale of 0–10, where 0 indicated complete disagreement and 10 indicated complete agreement with the statement. The online questionnaire took approximately 10–15 min to complete. Data were collected from September to November 2021 (Russia) and March through December 2022 (France).

2.2 Safety

This was a retrospective study without product use. Subjects were informed that any reported adverse events would be recorded. No adverse events or safety issues were identified during the study.

2.3 Data Analysis

Data were analyzed across the total population of all subgroups, then by subgroup. Success criteria were defined as agreement with the statements of at least 70% of the sample scoring ≥ 7 on the scale of 0–10. The proportions of respondents agreeing with the individual statements were calculated using the denominator for the total sample within each analysis group. Frequency distributions with 95% confidence intervals (CIs) were calculated of the percentages of respondents agreeing with the statements using a normal approximation. Missing data were not imputed. Additionally, the interquartile range (IQR) was calculated (IQR is the difference between the upper and lower medians of the data for representation of the central tendency and spread of the data).

3 Results

3.1 Experiences, Severity, and Treatment of Constipation

For the Russia cohort, 82.2% of respondents experienced an episode of constipation within the previous 2 weeks and 99.4% experienced an episode of constipation within 8 weeks. The median duration of the most recent episodes of constipation was 4 days (IQR 6 days). Median severity of the most recent constipation episode was 6 on a scale of 0 (not severe) to 10 (extremely severe) for females aged 25–54 years and pregnant females (IQR 2) and mothers with babies (IQR 3) and 7 for males and females aged 60–80 years (IQR 3). Overall, 99.5% of the respondents treated themselves for their most recent episode of constipation. The most frequently used treatment was the microenema (98.5%), followed by an oral laxative (38.7%) and a natural alternative such as eating more fiber or drinking more water (17.1%). Suppositories and enemas were least used (3.9% and 2.4%, respectively).

For the France cohort, 68.3% of respondents experienced an episode of constipation within the previous 2 weeks and 95.9% experienced an episode of constipation within 8 weeks. The median duration of the most recent episodes of constipation was 4 days (IQR 5.5 days). Median severity of the most recent constipation episode was 6 (IQR 2) for both groups (females aged 25–54 years

Table 2 Constipation and quality of life (higher score indicates greater impact on QoL)

Group	Median score (IQR) Russia	Median score (IQR) France
Cause of negative emotions[a]	7.8 (3.0)	6.0 (3.3)
Impact on daily life[a]	7.0 (2.5)	6.3 (2.2)
Cause of embarrassment[a]	6.7 (4.3)	6.7 (3.3)
Interferes with daily activities[a]	6.0 (3.0)	6.0 (3.0)
Indicates something is seriously wrong with the baby[b]	10 (2.0)	NA
Causes baby to experience pain[b]	10 (1.0)	NA
Bad for baby[b]	10 (1.0)	NA

NA not applicable

[a]Asked of all respondents except mothers of babies

[b]Asked of only respondents who were mothers with babies

and males and females aged 60–80 years). Overall, 99.4% of the respondents treated themselves for their most recent episode of constipation. The most frequently used treatment was the microenema (63.6%), followed by oral laxatives (56.3%) and a natural alternative, such as eating more fiber or drinking more water (36.6%). Suppositories and enemas were least used (17.6% and 3.9%, respectively).

3.2 Constipation and Quality of Life (QoL)

Respondents rated how constipation affected a variety of QoL attributes on a scale of 0 (not severe at all) to 10 (extremely severe). Constipation affected quality of life in all groups in both Russia and France cohorts. It severely limited daily life and activities and caused negative emotions and embarrassment. Mothers with babies showed great concern that constipation indicated a serious and painful condition and was bad for their babies (see Table 2 for overall results).

3.3 Perception of Treatments for Constipation

Respondents were asked their agreement of statements regarding oral laxatives, suppositories, and microenemas for these parameters: ease of use, works within 15 min, comfortable experience during use, cause for concern, reliability, and relieving the worry of constipation. In addition, in the Russia cohort, mothers of babies rated the happiness of their baby after use, and pregnant females rated their agreement that local action was better for their unborn baby.

In the Russia study, respondents rated their experiences with each treatment independently. Due to the smaller sample in the France cohort, respondents were grouped into those who used oral laxatives and the microenema, and those who used suppositories and the microenema, all within the 3 months of enrolling in the study.

For the overall Russia cohort, almost all respondents agreed that the microenema was easy to use (93.5%), worked within 15 min (90.7%), provided a comfortable experience (91.3%), did not cause concern (90.9%), and was reliable and relieved the worry of constipation (91.5% and 86.8%, respectively).

While the majority of users of oral laxatives and suppositories agreed that these treatments were easy to use (76.5% and 60.6%, respectively), only half or fewer respondents agreed with most of the other statements. About half viewed oral laxatives and suppositories as a comfortable experience (50.6% and 53.3%, respectively), and using these treatments did not cause concern (48.0% and 46.8%, respectively). Suppositories were viewed as reliable by 59.7% of respondents, oral laxatives by only 40.3%. The majority of respondents did not agree that oral laxatives worked within 15 min (66.3%) or relieved the worry of constipation (60.6%). For suppository users, 55.7% did not agree that suppositories worked within 15 min nor did they relieve the worry of constipation for 56.9% of users.

In the group of mothers with babies < 3 years old, 93.5% agreed that their baby appeared happier after the parent administered the microenema. About half agreed that their baby appeared happier after administration of a suppository (50.5%) or an oral laxative (48.5%).

In the group of the pregnant female respondents, 94.3% agreed treatment with the microenema was better for their unborn baby. Agreement was 60.6% for suppositories and 30.7% for oral laxatives (see overall results from Russia in Table 3).

The subgroup of oral laxative and microenema users in the France cohort had a higher percentage of respondents agreeing that the microenema worked in 5–20 min, was comfortable to use, reliable, and provided less cause for concern and worry about constipation than oral laxatives. Only ease of use was not different, with the majority agreeing that both the microenema (84.5%) and oral laxatives (87.7%) were easy to use. Both oral laxatives and the microenema exceeded the 70% agreement threshold for ease of use, but only the microenema met the criteria for fast effect time and comfort.

The subgroup of suppository and microenema users had a higher percentage of agreement for all attributes tested. As with the other subgroup, the majority agreed that both the microenema (85.2%) and suppositories (76.5%) were easy to use. The microenema exceeded the 70% threshold for time to work, comfort, reliability, and relief of worry about constipation, while suppositories did not meet the threshold for these attributes.

See subgroup results from France in Table 4.

Table 3 Agreement with statements regarding oral laxatives, suppositories, and microenemas (Russia)

Statement	Agree with statement—score ≥ 7 Russia	
Easy to use	*N*	Number of responses ≥ 7 (%)
Oral laxatives	1118	855 (76.5)
Suppositories	325	197 (60.6)
Microenema	1118	1045 (93.5)
Works in 15 mins	*N*	Number of responses ≥ 7 (%)
Oral laxatives	858	289 (33.7)
Suppositories	255	113 (44.3)
Microenema	858	778 (90.7)
Provides comfortable experience	*N*	Number of responses ≥ 7 (%)
Oral laxatives	858	434 (50.6)
Suppositories	255	136 (53.3)
Microenema	858	783 (91.3)
Does not cause concern	*N*	Number of responses ≥ 7 (%)
Oral laxatives	1118	537 (48.0)
Suppositories	325	152 (46.8)
Microenema	1118	1016 (90.9)
Reliable	*N*	Number of responses ≥ 7 (%)
Oral laxatives	858	346 (40.3%)
Suppositories	255	512 (59.7%)
Microenema	858	785 (91.5%)
Relieves worry of constipation	*N*	Number of responses ≥ 7 (%)
Oral laxatives	1118	441 (39.4)
Suppositories	325	140 (43.1)
Microenema	1118	970 (86.8)
Baby appears happier after use[a]	*N*	Number of responses ≥ 7 (%)
Oral laxatives	260	126 (48.5)
Suppositories	70	35 (50.0)
Microenema	260	243 (93.5)
Local action better for unborn baby[b]	*N*	Number of responses ≥ 7 (%)
Oral laxatives	261	80 (30.7)
Suppositories	71	43 (60.6)
Microenema	261	246 (94.3)

[a]Additional statement asked of mothers with babies

[b]Additional statement asked of pregnant females

3.4 Perception and Experiences of the Use of Microlax Microenema

One aim of this research is to understand perceptions and attitudes about the use of the microenema; therefore, the questionnaire included statements about quality of life, comfort, use, and reliability with the microenema.

In the Russia cohort, 63.9% of respondents used the microenema as the first treatment for their most recent constipation episode, while in the France cohort, the majority (51.4%) used it as the second treatment option after natural remedies.

The study explored respondents' concern or anxiety about using the microenema. Before using it for the first time, overall concern for both cohorts had a median score of 5.0 out of 10; however, this concern dropped significantly after respondents used it. In the overall Russia cohort, concern about the ease of use dropped by 50% after the first use. In the France cohort, concern dropped by 20% after the first use and by 47.2% when considering future uses. Concern over using the microenema is presented by group in Table 5.

Quality of life issues such as feeling in control, not interfering with the day's activities, ability to socialize, and feeling relaxed after using the microenema were highly agreed by all respondents. The Russia cohort exceeded the 70% threshold for all statements, while the France cohort reached the threshold for getting on with their day but were not quite as high for the other QoL attributes.

The comfort of using the microenema was highly agreed in both cohorts (92.2% in Russia and 73.7% in France). The local action provided by the microenema was seen as a benefit. In the Russia cohort overall, 94.3% of respondents agreed that it "works just where it is needed." In addition (data not shown), 95.0% of pregnant females agreed that since it "works just where it is needed, it is better for my unborn baby," while 93.1% of mothers with babies under 3 years old agreed microenemas were better for their baby than something that works through their system. Of the group of respondents between 60 and 80 years old, 89.5% agreed that using the micro-enema "avoids the need to take another pill." In the France study, although not quite reaching the 70% agreement threshold, 69.6% of the respondents agree that it works just where it is needed, and 69.2% of the 60–80-year-old respondents agree that it allows them to avoid taking another pill.

Both cohorts agreed (and exceeded the 70% threshold) that the microenema was easy to use and reliable (see overall results in Table 6).

4 Discussion

All participants met the criteria for being (or their child being) sufferers of occasional constipation. Almost all participants had administered a treatment to themselves or their child (for mothers of children < 3 years old) for their most recent episode of constipation. For the few who did not (six in the Russia cohort, three in the France cohort), all had used a self-treatment for an earlier episode as defined in the protocol (within 12 weeks of study enrollment).

When asked about quality of life issues caused by their constipation, both the Russia and France cohorts reported

Table 4 Agreement with statements regarding oral laxatives, suppositories, and microenemas (France)

Statement	Agree with statement—score ≥ 7 Microenema versus oral laxative ($n = 171$)	Agree with statement—score ≥ 7 Microenema versus suppository ($n = 81$)
Easy to use	Number of responses ≥ 7 (%)	Number of responses ≥ 7 (%)
Oral laxatives	150 (87.7)	
Suppositories		62 (76.5)
Micro-enema	146 (85.4)	69 (85.2)
Works in 5–20 mins	Number of responses ≥ 7 (%)	Number of responses ≥ 7 (%)
Oral laxatives	42 (24.6)	
Suppositories		48 (59.3)
Microenema	122 (71.3)	58 (71.6)
Provides comfortable experience	Number of responses ≥ 7 (%)	Number of responses ≥ 7 (%)
Oral laxatives	75 (43.9)	
Suppositories		49 (60.5)
Microenema	124 (72.5)	62 (76.5)
Does not cause concern	Number of responses ≥ 7 (%)	Number of responses ≥ 7 (%)
Oral laxatives	86 (50.3)	
Suppositories		47 (58.0)
Microenema	118 (69.0)	55 (67.9)
Reliable	Number of responses ≥ 7 (%)	Number of responses ≥ 7 (%)
Oral laxatives	55 (32.2)	
Suppositories		49 (60.5)
Microenema	116 (67.8)	57 (70.4)
Relieves worry of constipation	Number of responses ≥ 7 (%)	Number of responses ≥ 7 (%)
Oral laxatives	58 (33.9)	
Suppositories		41 (50.6)
Microenema	112 (65.5)	57 (70.4)

Table 5 Concern over microenema use

Group	Russia				France			
Time	Before first use median (IQR)	After first use—median (IQR)	Percent change—median % (IQR)	Future use median (IQR)	Before first use median (IQR)	After first use—median (IQR)	Percent change—median % (IQR)	Future use median (IQR)
Females, 25–54 years	5.0 (5.0) n=265	2.0 (4.0)	−50.0 (74.4)	1.0 (2.0)	6.0 (3.0) n = 280	4.0 (3.0)	−23.6 (65.6)	2.0 (2.0)
Pregnant females, ≥ 25 years	5.0 (6.5) n=261	20. (4.0)	−37.5 (80.0)	0.0 (3.0)	NA	NA	NA	NA
Mothers with babies < 3 years old	5.0 (5.8) n=260	1.0 (3.0)	−57.1 (88.3)	0.0 (2.0)	NA	NA	NA	NA
Males and females, 60–80 years	6.0 (4.0) n=332	2.5 (3.0)	−50.0 (54.9)	1.0 (3.0)	4.0 (3.0) n = 237	2.0 (1.75)	−16.7 (50.0)	3.0 (2.0)
Total	5.0 (5.0) n=1118	2.0 (4.0)	−50.0 (80.0)	1.0 (2.0)	5.0 (3.0) n = 517	3.0 (2.0)	−20.0 (60.0)	2.0 (2.0)

Scale: 0 = completely disagree; 10 = completely agree

Table 6 Perception and experiences of the use of microenema

Statement	Percent agree with statement—Russia	Percent agree with statement—France
Quality of life		
Because I have an idea of when it will work, I feel more in control of my day[a]	88.8	65.0
Because it is reliable, it allows me to get on with my day[a]	88.3	70.3
Because it is reliable, it relieves the worry of constipation	81.7	67.6
Because it is reliable, I feel relaxed and able to socialize[a]	83.9	63.1
When it relieves baby's constipation, my baby appears happier[b]	93.5	NA
When it relieves baby's constipation, I feel happier[b]	94.2	NA
Comfort		
It allows a comfortable toilet experience	92.2	73.7
It works just where it is needed (local action)	94.3	69.6
Ease of use		
It is easy to use	93.2	77.0
Reliability		
It is a reliable choice because every time I use it, it helps to relieve constipation within the expected time[c]	93.6	80.3

NA not applicable

[a]Asked of all respondents except mothers with babies

[b]Asked to only mothers with babies

[c]Expected time: in Russia, it is noted as within 15 min; in France it is within 5–20 min

a high level of negative emotions and embarrassment (Table 2). They noted that constipation negatively impacted their daily lives and interrupted their normal activities. In short, even episodes of occasional constipation diminished their quality of life and well-being. These reactions align with the quality of life issues seen in studies of people with chronic constipation, who noted feelings of isolation and shame [6, 7].

The agreement among mothers with babies who exhibited occasional constipation had the highest possible score of 10 for the three main attributes, and constipation indicated that something was seriously wrong with their child, it caused pain and was bad for the child (Table 2). Studies of parents responsible for children with chronic constipation report self-doubt, lack of information, and a negative impact on their child's quality of life [17, 18]. Similarly, the finding from this study indicates that caring for a child who experiences only occasional constipation elicits a high level of concern in their mothers.

Interestingly, the Russia cohort had a higher median agreement score for the quality of life issues of "causes negative emotions" and "impacts daily life" than the France cohort, indicating that their level of concern is greater. Prestudy listening exercises in Russia (unpublished data) revealed that many people feel a level of self-blame if they need to use treatments to relieve their constipation, believing it means they are not doing enough to prevent it in the first place. Coupled with that is the belief that they must self-treat to avoid embarrassment of going to the doctor if the condition does not resolve. These conflicting feelings may contribute to the impact on quality of life.

In this study, awareness and usage of OTC treatments for occasional constipation were high. This is not unexpected, since an inclusion criteria was having used OTC treatments, including Microlax microenema, prior to entering the study. Therefore, this population is ideal for assessing all three OTC treatment options.

The Russia cohort reached and exceeded the 70% threshold for all assessed attributes that included ease of use, reliability, worked within a set time, relieved worry, comfortable experience, among others, from using the microenema. Mothers thought their babies were happier after using the microenema to relieve their constipation, and pregnant females felt it was better for their unborn babies (Table 3).

The France cohort also demonstrated a higher agreement with these attributes for the microenema versus oral laxatives and suppositories (Table 4), but the response was not as high as in Russia. Investigation by the research team and unpublished data show limited information on consumer-facing healthcare websites and in scientific literature about microenemas in Europe, which may have had an impact on awareness of the treatment.

In this study, we explored perceptions of and barriers to using microenemas. Microenemas are designed to work locally where needed (rectally). Proper use requires preparation and careful adherence to the product instructions

and, consequently, can feel somewhat intimidating before the first use. Study participants rated the concern they felt before the actual use as moderate (5 out of 10, Table 5). After actually using the microenema for the first time, the concern for the next and future uses dropped considerably. The highest level of concern or anxiety was anticipating using the product, while the actual use was far less daunting.

The study data show that using the microenema contributed to an increased quality of life (Table 6). Respondents felt a high level of control and developed a level of confidence that the microenema with its local effect worked reliably and within a specified period of time. The sense of control allowed participants to go about their day without being concerned about being constipated or having an effect from a laxative at a later point. They felt more able to socialize. The positive effects of this treatment address and reverse the negative quality of life aspects reported in literature, such as isolation and shame.

4.1 Limitations

This trial was retrospective, so the potential for recall bias exists. This was controlled by ensuring a minimum amount of time between the use of treatments and trial participation (median time since respondents experienced constipation was 1 week before the trial) and selecting a 0–10 graphic rating scale for all questions to provide sufficient response options to enable respondents to select the answers that most closely represent their views. Steps to minimize misclassification of constipation included use of the Rome IV diagnostic criteria as well as timing of constipation episodes in the screening questions to ensure only those with occasional constipation entered the study. Another potential limitation was that all respondents were users of OTC treatments for constipation and had to have used Microlax microenema more than one time, which was believed necessary for the collection of robust RWD; therefore, it does not capture the opinions of others who have not used these treatments or who were single-time microenema users. Efforts to prevent measurement error from the survey included rigorous preparation of the questionnaire following accepted approaches, pretesting the statements to ensure they were clearly understood and listing the statements in random order to prevent assimilation effects. Through validity checks, some respondents whose data were deemed unreliable due to providing the same answer throughout, not answering all questions, or taking insufficient time to complete the questionnaire properly were replaced by other participants. Additionally, respondents received a minimal incentive for completing the questionnaire. To control for unconscious bias, the incentive value complied with industry accepted ESOMAR guidelines to ensure it was proportionate and aligned with legal requirements for the locations of the study, appropriate for the audience and the nature of the research.

5 Conclusions

Occasional constipation will affect most people at some point in their lives and is often managed with lifestyle changes and/or the use of over the counter treatments. However, as shown by the results of this real world evidence study, experiencing even occasional bouts of constipation can negatively affect quality of life and well-being in women aged 25–54 years and older men and women aged 60–80 years who experience it, as well as parents who are responsible to manage it in their children. Concerns and quality of life issues found in the chronic constipation patient population (based on literature) are observed in occasional sufferers as well.

OTC treatments include oral laxatives, suppositories, and microenemas. Microlax, the microenema used in this study, showed superior benefits in the relief of occasional constipation compared with oral laxatives and rectal suppositories. Additionally, once consumers overcome their initial trepidation of the first time use of the microenema, they agreed that it provided targeted local (not systemic), reliable, and rapid relief of occasional constipation. This enables the consumer to regain a feeling of control and in turn, provides a positive impact on quality of life and well-being.

Acknowledgements Medical writing support for the preparation of this manuscript was provided by Carol Feinberg of Carol Feinberg Consulting LLC and was funded by Kenvue Inc. The authors acknowledge Robert Friedline and Guillaum Hirsch for critically reviewing the manuscript.

Declarations

Funding This work was funded in full by McNeil AB, part of Kenvue Inc.

Competing Interest The authors are either employees or were compensated for their services by McNeil AB or Johnson & Johnson GmbH; however, there are no competing interests related to this publication.

Financial Interests The authors declare that they have no financial interests in the publication of this manuscript.

Non-financial Interests None.

Data Availability The data that support the findings of this study are not openly available due to reasons of sensitivity and are available from the corresponding author upon reasonable request.

Ethics Approval The study was conducted in accordance with ICH Good Clinical Practice, all applicable subject privacy requirements (including European General Data Protection Regulation), and the

guiding principles of the current version of the Declaration of Helsinki. In addition, approval to conduct the study was pursued with Independent Ethics Committees in the respective countries; however, it was deemed to be unnecessary for this type of research [based on Comité de Protection des Personnes (France) and federal law nr 61-FZ (Russia)]. All participants, or guardians as appropriate, provided informed consent to participate.

Consent to Participate All participants, or guardians as appropriate, provided informed consent to participate.

Consent for Publication Not applicable.

Code Availability Not applicable.

Authors' Contributions S.R. and K.L. oversaw the conduct of the study and the analysis of the data. C.S. provided oversight of the research and background for the research program. All authors contributed to the interpretation of the data, results of the work, and the writing of the manuscript. All authors read and approved the final manuscript.

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