

Review Article

Revolutionizing Constipation Treatment: The Role of Oral Vibrating Capsules and Beyond - A Narrative Review

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ABSTRACT

Constipation has been a prevalent global problem affecting around 2.5 million people, with 92,000 hospital admissions in the US, with spending amount more than \$1 billion annually. It is a significant cause of morbidity, especially in the geriatric population, resulting in extended hospital stays and institutional care settings. In response to this worrying trend, various pharmacological and non-pharmacological interventions have been embraced to produce promising outcomes focusing on a multifaceted approach tailored to individual needs. Non-pharmacological measures include dietary and lifestyle changes, such as increasing fiber consumption, staying hydrated, and engaging in regular physical activity with biofeedback therapy and pelvic floor rehabilitation. In addition to the non-pharmacological therapies, over-the-counter laxatives provide momentary relief, while prescription drugs are used for severe cases or underlying disorders. Despite the various available conventional pharmacological and non-pharmacological therapies recently, an oral vibrating capsule (VC) was approved by the US Food and Drug Administration (FDA) in August 2022 to treat chronic idiopathic constipation in individuals who have not found relief from current laxative medicines for at least a month. The vibrating capsule (VC) works on the principle of psychotherapeutics that increases motility and colonic peristalsis and reduces constipation and related symptoms in individuals with Chronic Idiopathic Constipation.

Key words: Vibrating Capsule, Constipation, Functional constipation, Gastric Motility, Colonic Transit

Constipation has been a common global problem for many years, and it leads to around 2.5 million doctor visits with 92,000 hospital admissions in the US. Female sex, advanced age, inactivity, low-calorie intake, low-fiber diet, taking numerous drugs, low income, and low educational attainment are risk factors for constipation. Women experience constipation three times more frequently than men do, and they are twice as likely to make doctor appointments for the condition [1, 2]. According to studies, women often have slower bowel movements than men do, and many of them endure constipation during their menstrual cycle. Non-White people are 1.3 times more likely than White people to experience constipation, and families with lower socioeconomic positions experience it far more frequently [3].

The yearly cost of treating constipation in the United States is estimated to be \$1 billion, which includes substantial expenses related to purchasing laxatives, which amount to

several hundred million dollars each year [4]. Constipation issues are usually not fatal, but they can be more dangerous for the elderly and frequently result in hospital stays and long-term placement in institutional care settings [5]. These costs show the significant financial toll that constipation takes on the healthcare system and emphasize the need for efficient management techniques to lessen the toll on one's health and finances [4]. The causes of constipation can be divided into primary (slow transit or outlet obstruction) or due to secondary causes like food habits, anatomical abnormalities, neurological conditions, drug side effects, and metabolic or endocrine diseases [6].

Landscape of constipation treatments

Current treatment options for constipation encompass a multifaceted approach tailored to individual needs. Dietary and lifestyle changes, such as increasing fiber consumption, staying hydrated, and engaging in regular physical activity, are

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frequently the first therapies [7]. The American Gastroenterological Association advocates for stepwise treatment, starting with conservative methods, gradually increasing fiber intake, and escalating to pharmacotherapy, like over-the-counter osmotic agents such as milk of magnesia and polyethylene glycol and sugar-based osmotic laxatives like lactulose and magnesium salts are commonly used. If these measures fail to provide adequate relief, the next step is introducing stimulant laxatives, such as bisacodyl or senna. Although these medications are cost-effective, they are recommended for momentary relief, as they often lead to tolerance, dependency, and electrolyte imbalances over time [8].

For refractory cases or certain underlying disorders, prescription drugs such as prokinetics, secretagogues, and chloride channel activators are also popular choices for treatment [9]. For people with pelvic floor dysfunction, they include biofeedback therapy and pelvic floor rehabilitation methods. Surgical procedures like colectomy or rectopexy may be considered in extreme situations [10].

Emergence of Vibrating Capsule Technology

Despite all the above-mentioned therapies, for individuals who are struggling with constipation symptoms to achieve long-term symptom control and improve their quality of life, there was a significant milestone achieved in the year 2022 when the FDA approved vibrating capsules in treatment for individuals who have not found relief from current laxative medicines for at least a month [11]. The vibrating capsules (VCs) were initially introduced by Ron, et al. as a secure and prosperous method of encouraging mean weekly spontaneous bowel movements (SBMs) in individuals with Chronic Idiopathic Constipation (CIC) with an physiological idea of increasing the motility and reducing the constipation by mechanically inducing regular peristaltic waves in the large intestine [12].

Mechanism of vibrating capsule for chronic constipation

A vibrating capsule is a novel, miniaturized capsule device developed as an alternative non-pharmacological treatment modality for gut dysmotility. The VC system comprises a single-use capsule and a control pod that activates the capsule using an electromagnetic signal [13]. It relieves constipation by increasing gastrointestinal motility and relaxing sphincters through parasympathetic and local reflexes. It comprises two attached segments enclosed in a shell that can move independently of one another. The two segments enclosed a ferromagnetic shaft and solenoid inside them.

The ferromagnetic shaft at one end is connected to the segment employing a biasing spring. In contrast, the other end of the shaft is free to move axially inside the other segment through the lumen of the solenoid, which is connected to the inner surface of the other segment using a bracket. When the electric current runs through the solenoid, the ferromagnetic shaft and the solenoid are pulled toward each other. When the

electric current is stopped, the biasing and connecting springs assume their initial unstressed lengths, with both segments being forced to move in opposite directions toward their initial disposition, thus creating vibrations in the capsule [14].

DISCUSSION

The use of vibrating capsules represents a novel, non-pharmacological intervention for chronic idiopathic constipation (CIC). Compared to traditional pharmacological therapies, which are often associated with poor patient adherence due to side effects and diminishing efficacy, the vibrating capsule offers a mechanical approach that aligns with patient preferences for non-drug options [15]. Its approval by the FDA and subsequent clinical trials highlight its efficacy in increasing spontaneous bowel movements (SBMs) and complete spontaneous bowel movements (CSBMs) with minimal adverse effects [16]. Initial investigations into vibrating capsules demonstrated their safety and potential efficacy. In a non-randomized, open-label study by Ron et al., 26 healthy volunteers experienced a significant increase in bowel movements from 2.19 to 3.79 per week ($p < 0.001$). While transient adverse events such as mild abdominal discomfort were reported, no severe side effects were noted [15].

A notable phase 3 randomized, double-blind, placebo-controlled trial involving 312 patients demonstrated that the vibrating capsule significantly improved bowel symptoms and quality of life compared to placebo. Specifically, 39.3% of participants using the vibrating capsule achieved an increase of at least one complete spontaneous bowel movement per week, compared to 22.1% in the placebo group. A post hoc analysis focusing on patients with severe chronic constipation revealed that the vibrating capsule significantly enhanced constipation-related symptoms and health-related quality of life, affirming its efficacy and safety across the spectrum of chronic constipation severity [17]. In addition to the previously mentioned studies, a randomized, double-blind, placebo-controlled, multicenter trial published in 2022 further evaluated the efficacy and safety of vibrating capsules in patients with functional constipation. The study focused on patients aged 18 to 80 with Functional constipation, where patients were randomly assigned in a 1:1 ratio to receive a Vibrating capsule or placebo treatment for six weeks (two capsules per week) after a two-week baseline period; VC was found to promote defecation, as well as ameliorate symptoms [18].

A recent systematic review conducted by Math and colleagues evaluated the effectiveness of the vibrating capsule in treating chronic idiopathic constipation. The researchers searched multiple databases, including PubMed, Embase, International Clinical Trials Registry Platform, Cochrane Library, and two pre-print servers (medRxiv.org and Research Square) until December 31st, 2022. The study identified pre-clinical and clinical original studies assessing the role of the vibrating capsule in patients with chronic constipation. The

results showed that the group receiving the vibrating capsule had a significantly higher number of spontaneous bowel movements per week than the group receiving the sham capsule. Additionally, the proportion of patients experiencing at least one complete spontaneous bowel movement per week increased significantly. Mild adverse events, such as vibration sensation, diarrhea, and abdominal discomfort, were observed, but no treatment-related severe adverse events were reported. The vibrating colon-stimulating capsule is a promising treatment option for chronic constipation, with a favorable efficacy and safety profile [19].

A recent systematic review by Haghbin et al. aimed to compare the effectiveness and safety of vibrating capsules (VC) in treating chronic constipation after conducting a comprehensive literature search through various databases, including Embase, PubMed/MEDLINE, Cochrane Central, Web of Science, Global Index Medicus, and Google Scholar, up until June 14th, 2023 and using the DerSimonian-Laird method and random effects model to analyze the data, and calculated odds ratio (OR) and mean difference (MD) for proportional and continuous variables, respectively with the confidence interval (CI) was set at 95%. A p value of <0.05 found that of the 117 articles four studies with 705 patients were selected to compare VC and placebo/sham treatment. The pooled complete spontaneous bowel movement (CSBM),

defined as bowel movement without the use of laxatives within the last 48 hours, with a sense of complete evacuation, did not show statistical improvement with VC (MD =0.153; 95% CI : -0.218 to 0.523; p=0.422).

However, spontaneous bowel movement (SBM), defined as bowel movement without the use of laxatives within the last 48 hours, showed statistical improvement with VC (MD =0.159; 95% CI: 0.095 to 0.223; p<0.001) without an increase in the pooled adverse events (OR =1.431; 95% CI: 0.702 to 2.916; p=0.324) [13]. However, in a systematic review by Saeed et al, three Randomized Controlled Trials (RCTs) were analyzed with 601 patients. The analysis found that there was no significant difference between the administration of VC and placebo in terms of responder rate, change from baseline in CSBM, change from baseline in SBM, and the occurrence of any adverse event [20]. Furthermore, several studies have shown that patient adherence and satisfaction often improve when treatment options align with these preferences. Various studies have suggested the safety of vibrating capsules in treating constipation with well-tolerated and no severe adverse events [21]. Studies evaluating the effectiveness of VC have indicated that the number of vibrations also affects the capsule's effectiveness, with at least two vibration sessions per day proving superior and significantly increasing the number of complete spontaneous bowel movements [17].

Table 1: Recent Systematic review/Meta-analysis studies

Author and year of study	Study Design & Population	Findings	Limitations
Math et al. (2023) [19]	Systematic review (clinical & pre-clinical studies); patients with chronic constipation	VC increased weekly SBMs and CSBMs; mild adverse events, no severe effects	Limited sample size; variable study quality
Haghbin et al. (2024) [12]	Meta-analysis of 4 RCTs (705 patients); DerSimonian-Laird method	Significant improvement in SBM (MD = 0.159; p<0.001); no increase in adverse events	No significant effect on CSBM; heterogeneity in population
Saeed et al. (2023) [20]	Meta-analysis of 3 RCTs (601 patients); Functional constipation	No significant difference in responder rate, SBM, CSBM, or adverse events vs. placebo	Small number of trials; short follow-up; subjective reporting bias

Future directions

While the introduction of vibrating capsules marks a promising advancement in managing chronic idiopathic constipation, further research is essential to optimize their clinical use. Future studies should focus on identifying patient subgroups most likely to benefit from this technology, potentially guided by biomarkers or baseline motility assessments. Standardizing vibration parameters—such as frequency, duration, and timing—may help enhance therapeutic outcomes. Long-term safety and efficacy data are also needed to assess sustained benefits and adherence beyond short-term trials. Comparative studies with existing pharmacologic and behavioral therapies would clarify the optimal role of vibrating capsules in current

treatment algorithms. Moreover, real-world evidence from diverse populations and healthcare settings can provide valuable insights into practicality, accessibility, and patient satisfaction. As technology evolves, integrating biofeedback mechanisms and smart monitoring features within capsules may further personalize and improve constipation care.

CONCLUSION

Patients with Chronic Idiopathic Constipation often seek alternatives to pharmacotherapy for reasons that extend beyond clinical efficacy. Many individuals perceive devices like the vibrating capsule as more "natural" or less invasive compared to traditional medications. This preference aligns with a broader

public trend of avoiding chronic pharmacotherapy due to concerns about long-term side effects, medication dependency, and a desire for non-chemical interventions. Additionally, devices offer a sense of technological advancement and innovation, which can appeal to patients dissatisfied with pharmacological treatments or adverse effects. However, since the patient's various internal and external factors in the clinical environment still need to be underscored to understand trends in the intervention's efficacy, this promising technology may be helpful for constipated individuals who are less responsive to pharmaceutical interventions. However, well-designed, placebo-controlled, more extensive studies are needed to confirm these findings.

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