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Recognizing and Defining Occasional Constipation: Expert Consensus Recommendations

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Constipation is a common problem, affects 15% of the population, and is often self-diagnosed and self-managed. Over the past 3 decades, there have been significant advances in our understanding and management of chronic constipation, with the emerging recognition that occasional constipation (OC) is another subtype that falls outside current classifications. The purpose of this review was to describe the process of developing and proposing a new definition for OC based on expert consensus and taking into consideration the multifactorial nature of the problem such as alterations in bowel habit that include stool frequency and difficulty with stool passage, perception of the sufferer, duration of symptoms, and potential responsiveness to treatment. Leading gastroenterologists from 5 countries met virtually on multiple occasions through an online digital platform to discuss the problem of OC and recommended a practical, user-friendly definition: "OC can be defined as intermittent or occasional symptomatic alteration(s) in bowel habit. This includes a bothersome reduction in the frequency of bowel movements and/or difficulty with passage of stools but without alarming features. Bowel symptoms may last for a few days or a few weeks, and episodes may require modification of lifestyle, dietary habits and/or use of over-the-counter laxatives or bulking agents to restore a satisfactory bowel habit." Prospective studies are required to validate this definition and determine OC prevalence in the community. This review highlights current knowledge gaps and could provide impetus for future research to facilitate an improved understanding of OC and development of evidence-based management guidelines.

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INTRODUCTION

Constipation is experienced by most people at some point (1) and is typically self-diagnosed and self-treated. However, the definitions of constipation mainly focus on chronic constipation (CC) and often use a stool frequency threshold such as <3 bowel movements/week (2). This approach fails to recognize the wide variation in the "normal" frequency of bowel movements. For example, in 1 study, 96% of adults reported 3–21 bowel movements/week (3). More frequent stools were reported by White than non-White participants (7.8 vs 6.0 stools/week, $P < 0.0001$) and men vs women (9.2 vs 6.7 stools/week, $P < 0.0001$) (4). Focusing on stool frequency fails to recognize that most constipated individuals are bothered not by infrequent bowel movements but by symptoms suggestive of defecation difficulties, e.g. straining, need for manual maneuvers, passage of hard stools, and/or a sense of incomplete evacuation (4–9). Thus, the subjective perception/experience of what constitutes a normal bowel habit varies widely. Constipation has a broad spectrum of symptoms, duration, severity, and impact in each individual, and many suffer from occasional constipation (OC) episodes not within any current CC definition—a problem often overlooked by clinical investigators and practitioners.

This review aims to familiarize the gastroenterology community with OC and to propose a definition encompassing stool frequency, difficulty with stool passage, individual perception, symptom(s) duration, and potential treatment responsiveness. We also discuss how to better recognize and manage OC.

BACKGROUND

The term "OC" originated from an expert panel in a US FDA over-the-counter (OTC) laxative monograph (10) and was referenced in a later OTC laxative monograph (11). "OC/short-term relief of constipation" is the approved indication for many OTC laxatives. However, OC was not clearly defined in either monograph or since. Thus, no generally agreed-upon or validated OC definition currently exists.

Despite no formal OC definition, we felt that it is a common problem affecting many people, as evidenced by OTC medicine sales, clinical experience, and limited studies. Laxatives comprise the second largest group of OTC digestive health products; the estimated cost was US$ 5,462.9 million in 2019 (12). The concept of OC is supported by a survey of 1,766 sodium picosulfate users finding that only 12% of patients took it regularly (22% once monthly or less, 18% 2–3 times/mo, 22% once weekly, 26% 2–6 times/wk), suggesting that most had OC (13). Of 561 individuals with constipation symptoms in the previous 12 months, 49% had experienced constipation between once a week and once a month (ISM Study, Boehringer-Ingelheim, Dulcolax Quant Growth

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potential. U&A study UK, 2016, data on file). In a cross-sectional, US population-based study, 4,702 participants had experienced constipation, and 1,128 of 4,702 (24%) met the Rome IV chronic idiopathic constipation (CIC) criteria (14). Interestingly, although 2,246 of 4,702 participants (48%) were currently taking medication for constipation, most of these (1,893/2,025, 93%) were only taking OTC medication (14). Thus, some of these individuals may have had OC; these findings indirectly support the likely high prevalence of OC in the community. However, reference to OC is scarce in publications. Furthermore, epidemiological data are lacking, partly because of the lack of an acceptable definition, and affected individuals typically do not seek professional health care. An OC definition is important because a large study of adults (15) found prevalence estimates of 9%–59% depending on which of 5 OC definitions was used. Prevalence rates of self-reported constipation of 21%–29.5% have been consistently reported (16–20). This contrasts with a meta-analysis of 45 studies reporting a pooled prevalence of 14% for CIC among over 261,000 adults (21). The prevalence was 2-fold higher among women, lower among Asians, and higher in persons of older age and lower socioeconomic status. A survey of 15,000 adults reported a prevalence of 14.9% during the past year (22,23).

METHODS

Owing to the lack of an OC definition, despite its high prevalence, and lack of awareness among healthcare professionals, we identified the need for scientific discourse and analysis. In October 2020, a group of experts in treating and conducting clinical trials/research in constipation and in developing clinical recommendations for constipation management met multiple times to discuss OC and to develop a framework for future dialog. Emphasis was placed on synthesizing a rational, practical OC definition to improve clinical recognition of OC to pave the way for improving management. We report our deliberations, an initial working OC definition, and some thoughts on management. Our objective was to stimulate further discussion working toward a broad consensus, greater recognition, and improved management of OC. Many laxative products are available for constipation. However, our focus was on OTC laxatives because these are more likely to be sought by people with OC for immediate relief. Prescription laxatives are typically used in the management of CC and other serious bowel disorders and are less immediately accessible to the individual with constipation.

Defining OC

Distinguishing OC from CC and other constipation types. OC and CC may be differentiated based on symptom duration and the presence of intervening symptom-free intervals. Whereas OC is an intermittent condition of short(er) duration, CIC is long(er) lasting with few or limited constipation-free intervals resulting in the affected person seeking professional health care, instituting lifestyle changes, and/or taking medication.

Several authorities, e.g., Rome Foundation (24), American Gastroenterological Association (AGA) (6,25), European Society of Neurogastroenterology and Motility (ESNM) (26), and the Indian Society of Gastroenterology (27), and the Italian Association of Hospital Gastroenterologists (AIGO)/Italian Society of Colo-Rectal Surgery (SICCR) consensus (28,29), have provided guidance on CC diagnosis and management strategies. Guidance for the management of some constipation subtypes, e.g. opioid-induced constipation (30), has also been developed.

By contrast, the definition of OC does not have a similar consensus. Some recent working OC definitions have included the following:

1. Constipation (straining with lumpy or hard stools or no bowel movement in the past 48 hours) that does not resolve on its own with time vs chronic sufferers needing prescription medication and/or medical intervention (31);
2. At least 2 of the following in the past 2 weeks: ≤3 defecations/wk, and/or straining, lumpy or hard stools, sensation of incomplete evacuation or obstruction or blockage, or manual maneuvers to facilitate at least 25% of defecations (32);
3. <3 bowel movements/wk for at least 2 weeks (but not for >12 weeks in the past 6 months). Presence of at least 1 other bowel symptom of constipation in at least 25% of defecations: hard stools or complete lack of loose or watery stools, straining during defecation, feeling of incomplete evacuation, abdominal discomfort, and bloating/distension (33).

Furthermore, these definitions developed for clinical trials have not been tested/validated, do not reflect the wide spectrum of OC experience, fail to provide a sufficient basis for well-informed OC management, and do not recognize the broad-spectrum nature of OC. Any definition needs to differentiate OC from other constipation forms, provide a comprehensive OC characterization, guide prescribers and pharmacists on managing OC, aid in communication with regulatory agencies, and stimulate further OC research.

Toward a new definition of OC. During wide-ranging discussions on defining OC, there was broad agreement that it must have practical utility; be patient-centric; and encompass consideration of stool frequency/infrequency, defecation difficulties, symptom duration, intervention requirement, and any tendency toward resolution. Acknowledging the wide variation of what constitutes OC, we considered it important that our definition be flexible and responsive and allow for individual heterogeneity ("and/or") rather than requiring that all criteria be met. Incorporating flexibility in the definition fits with Rome IV guidelines (34), which consider that bowel disorders are a continuum and not discrete entities. Variation in perception of what constitutes "normal" stool frequency is important because one person may be concerned and seek OTC medication or consult their doctor because of a reduction in stool frequency, whereas such a change may not concern another. Variation in perception also exists between different countries and cultures (e.g., normal bowel habits or treatment needs) and between doctors and researchers and those with constipation. Thus, the new proposed working OC definition should be all-inclusive, so that it relates to and is applicable across different geographic regions and cultures. We also considered that the definition should be "user-friendly" for new OC research. It is important for any new OC definition to exclude warning signs ("red flags") such as new onset of constipation in older patients or blood in stools that could indicate more serious conditions, such as colorectal cancer, that would require medical evaluation. It should also, however, be borne in mind that such "red flag" signs have low sensitivity and specificity in functional bowel disorders (35,36).

In developing our definition, we considered the following factors, taking into account that criteria for CC are not met:

1. Demographics of OC: While some groups, such as the elderly and females (21), seem to be more prone to OC and certain lifestyles (e.g., low dietary fiber, low level of physical activity), travel,

relocation, job stress, etc., have been linked to constipation risk (37), OC seems to affect a wide spectrum of people (young and old; both sexes); no established relationship between OC and any demographic or individual characteristics exists.

2. Duration: "Typical" OC duration is a few days or occasionally weeks with wide variation. According to Rome IV criteria, a person only has to experience constipation symptoms 25% of the time during 3–6 months for a CC diagnosis, but critically, symptom onset must be "at least 6 months prior to the diagnosis." A person with OC may have intermittent constipation lasting only days but recurring over many years. During our deliberations on differentiating OC from CC, an episode duration threshold of 3–6 months was considered; however, it was noted that a shorter period of days to a maximum of a few weeks (4) might be better because constipation could be related to a change in diet/routine (e.g., travel) possibly lasting several weeks. Therefore, we agreed to avoid setting any duration limits, trusting that "occasional" is self-explanatory and adequate. We accept that by not setting any firm duration limit, this leaves open the possibility of "overlap," with some patients potentially meeting OC and CC criteria; further research may delineate this better.
3. Frequency: Given the wide interindividual variation in what constitutes a "normal" pattern of bowel movements, our view is that we should define OC based on subjective patient experience, for instance, by referring to "perception of reduction in bowel movement frequency" rather than setting any arbitrary "threshold" frequency for OC.
4. History and course: The nature of OC means that symptoms will be occasional and relatively short-lived. Indeed, most patients, if asked, either will not remember or will not have a clear answer regarding how acute the onset of constipation was. Therefore, our consensus view is that defining onset is unlikely to be useful.
5. Bothersomeness and impact on wellbeing: CC can adversely affect quality of life (QoL) (38,39). For example, patients with dyssynergic defecation and slow-transit constipation had greater psychological distress and impaired health-related QoL vs controls, and these dysfunctions correlated with constipation symptoms (40). In another survey, constipation symptoms affected QoL of 52% of respondents, and among those who worked or attended school, 12% experienced reduced productivity and a mean of 2.4 days of absence in the month before the survey (8). Hard stools and straining were the top 2 severe symptoms while bloating, straining, and hard stools were the most common bothersome symptoms among respondents. Given the deleterious impact of CC, it is reasonable to suppose that constipation symptoms will likely affect those with OC and drive people to OTC medication. Hence, our proposed new definition accounts for the "bothersomeness" of symptoms and its impact.
6. Intervention need: as perceived by the affected person. Given the wide variation in OC severity/impact perceptions, the decision to try OTC medications (or not) may represent an unreliable indicator of actual severity. However, it should be acknowledged that if the effects of a condition are insufficiently bothersome to prompt an affected person to try to cure or alleviate them, then such a condition may not warrant definition and classification. Hence, we have included mention of seeking treatment in our proposed OC definition but do not consider this factor to be a central/critical part of the definition.
7. Responsiveness to intervention: Although it might be useful to include response to therapy in defining OC as indicating a relatively benign condition that commonly resolves itself or responds to OTC treatment, it is also true that it is inherent in the term "occasional" that OC is not persistent and, thus, if constipation does not respond to therapy and persists, then it is likely that the patient has CC. We concluded that, because including short duration in the definition covers part of this ground, responsiveness to treatment may not be appropriate for inclusion in the definition.
8. Causes and triggers: In acknowledging that travel, change in diet, relocation, stress, etc., seem to be common factors associated with OC, our consensus view was that we do not consider inclusion of causes/triggers in the OC definition to be useful at this point because the influence of such factors needs to be determined from prospective studies.

Considering the above, we propose the following OC definition for further discussion, debate, and refinement (Figure 1):

> "Occasional constipation can be defined as intermittent or occasional symptomatic alterations in bowel habit, in the absence of warning signs* for more serious conditions. The symptoms include a bothersome reduction in the frequency of bowel movements and/or difficulty with passage of stools. These symptoms may last a few days or a few weeks, and may require modification of lifestyle, dietary habits and/or use of over-the-counter laxatives or bulking agents to restore a satisfactory bowel habit."

*We emphasize that individuals experiencing blood in their stools, weight loss, or abdominal pain; those with a personal or family history of colon cancer; those or who have recently started a new medication that may be temporally related to the onset of constipation symptoms should consult their physician.

Management considerations

Although our primary purpose was to raise awareness of OC as a specific and poorly recognized condition and propose a working definition, we feel it is important to provide some perspectives on management. Detailed recommendations are, however, outside its scope. However, if symptoms of OC are recurrent or if "red flags" are present or based on findings on clinical evaluation, further investigation may be required.

Because most people with OC will not see a physician, any management guidelines or recommendations should be widely disseminated and available through pharmacies and public channels, providing reliable information and communicating important advice on consulting a physician where concerning symptoms or worsening of constipation occur. However, while it may be possible to develop some rational guidance on OC management for pharmacists and other healthcare providers, a "one-size-fits-all" algorithm would be difficult to achieve because OC pathophysiology(ies) is/are not fully understood. Table 1 summarizes key knowledge gaps; addressing these gaps may aid in developing future guidelines/recommendations.

There is no single homogeneous group of OC patients. Rather, etiology, symptom severity, and treatment responses are likely to vary. Assessing constipation severity is difficult because of the subjective nature of individual experiences of constipation. Thus, it may be better to gauge the impact of constipation on the affected

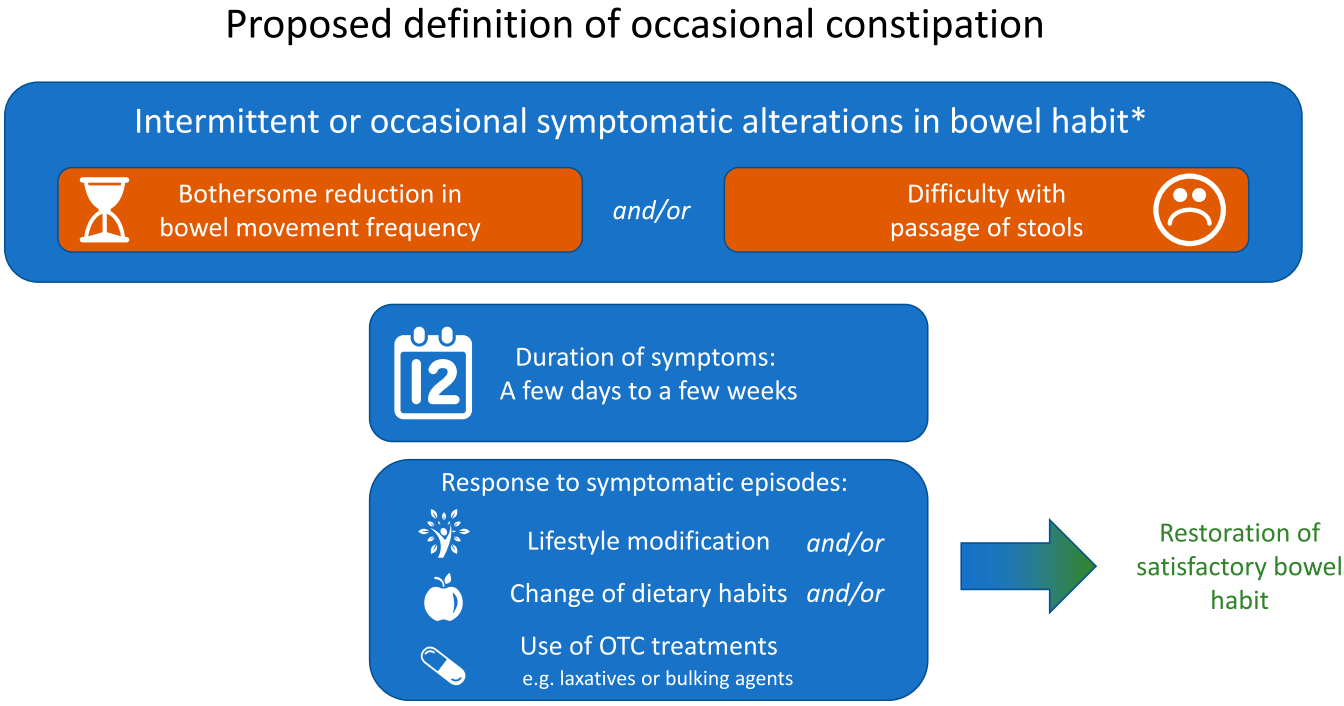

Figure 1. Proposed definition of OC. *Individuals experiencing blood in their stools, weight loss, or abdominal pain; those with a personal or family history of colon cancer; or those who have recently started a new medication that may be temporally related to the onset of constipation symptoms should consult their physician. OTC, over-the-counter.

person and determine what treatment types or actions they have already used. Basing treatment on a mode of action likely to address key symptoms while acknowledging the individual's preferences (patient-centricity) may be the most practicable treatment approach. Because lifestyle is important in OC, any future treatment guidelines should include lifestyle recommendations (diet, exercise), although the impact of such changes will take time to become apparent. In developing any guideline(s), it will be important to note that treatment choice in OC is likely to be a "one-shot" decision, and methodical, stepwise treatment plans will be less useful and possibly result in poor adherence. Consideration of what to avoid (e.g., avoiding excessive insoluble fiber intake in those with bloating) should also be a decision-making component.

Fiber has long been used to treat constipation and other gastrointestinal complaints (41–43). However, although increasing dietary fiber may eventually alleviate OC, people with OC may want a more immediate solution. Owing to the occasional nature of symptoms, OC is generally not treated with prescription medications. Patients who require persistent treatment with either OTC agents or prescription medications likely have CIC. Thus, we see little place for prescription medications in OC management.

For CC, a management approach guided by efficacy and cost typically begins with dietary fiber supplementation and stimulant and/or osmotic laxatives, followed, if necessary, by intestinal secretagogues and/or prokinetic agents, with peripherally acting μ-opiate antagonists as an option for opioid-induced constipation (6). A systematic review of efficacy and safety of OTC CC

Table 1. Overview of significant OC knowledge gaps

Gap	Description
Incidence and prevalence	Owing to a lack of agreed definition and reliable data, it is unclear what proportion of individuals experience OC and how it affects different demographics
Duration and frequency	Further study is needed to optimize the delineation between OC and CC, particularly where an individual may experience multiple episodes of constipation within a given time frame
Subjectivity	The proposed definition of OC is by necessity driven by subjective patient experience and perceptions of "normal" and "abnormal" bowel habits, which remain poorly understood
Responsiveness to interventions	Treatment response is difficult to assess for several reasons, including that OC is typically self-limiting; however, agreement on a definition may aid in designing suitable studies
Triggers	Factors believed to trigger OC episodes are many and variable, such that it was impractical to build consideration into the definition; further study is needed to understand causative factors and mechanisms

CC, chronic constipation; OC, occasional constipation.

treatments (44) reported good evidence for using the osmotic laxative polyethylene glycol and the stimulant senna; moderate evidence for psyllium (ispaghula), SupraFiber, magnesium salts, stimulants (bisacodyl, sodium picosulfate), fruit-based laxatives (kiwi, mango, prunes, figs), and yogurt with galacto-oligosaccharide/prunes/linseed oil; and insufficient evidence for using polydextrose, inulin, and fructo-oligosaccharide. Unfortunately, no such data are available for OC, reflecting the lack of an established definition. For short-term relief of constipation, it is reasonable to expect that established CC treatments should be of benefit in OC, with the caveat that a rapid onset of action will be preferable because individuals seeking OC relief generally want/expect a treatment that works quickly.

Any initial guidance on OC management will necessarily be based on our clinical judgment and data from OC trials, if possible. Another initiative would be to develop and institute a program to raise OC awareness, emphasizing the pros and cons of available treatments. Such a program could encourage pharmacists to engage with consumers for a clearer picture of their symptoms and help increase understanding of the prevalence and impact of OC and of patients' preferences around treatments. This could better inform management guidelines.

SUMMARY

In conclusion, we have tried to better define OC, recognizing the widely disparate nature of OC and an individual's perceptions and reactions to OC. Thus, our proposed working OC definition is necessarily imprecise. By highlighting this issue and identifying the knowledge gaps and by proposing features that could have value for its definition/diagnosis, we hope to stimulate further debate and contributions from the wider gastroenterology community, so that a more robust definition of OC may develop and gain broader acceptance. Further research is needed for a better understanding of the characteristics and prevalence of OC and gain insights into its management in the community. We trust that the proposed definition will serve as an impetus for such research and pave the way for greater recognition and understanding of OC.

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CONFLICTS OF INTEREST

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