# Laxative Use in the Community

Laxatives are commonly used for self-management of constipation in the community.

## 1. Introduction

Laxatives accelerate or induce defecation [1] and are often used in the management of constipation in the community [2]. Constipation, a common community problem globally [3][4], is frequently self-diagnosed and self-managed by community-dwelling adults [5]. Constipation represents a substantial cost in the community [6], particularly chronic constipation which is usually defined by a set of clinical symptoms known as the Rome criteria [7]; these criteria have been revised several times since their introduction in 1994 as Rome I criteria. Constipation also includes both chronic and sporadic constipation [8]. Most adults attempt to self-manage their constipation before consulting a healthcare professional [9]. Self-management often includes the use of laxative products, most of which may be purchased in pharmacies and elsewhere without prescription. However, failures in the self-management of constipation are frequent and lead to additional costs which add considerably to the financial burden of constipation in the community [10].

Laxative pharmaceutical products available without prescription are generally referred to as over-the-counter (OTC) laxatives. Classification of laxatives is based on the mode of action and the four main classes of OTC laxatives are bulk-forming laxatives, softeners/lubricants, contact/stimulant laxatives and osmotic laxatives [1]. This classification is commonly used worldwide and is incorporated in the World Health Organization's list of drugs for constipation as defined by the Anatomical Therapeutic Classification (ATC) [11]. For optimal management of constipation, healthcare professionals working in primary healthcare settings need to understand the extent of OTC laxative use in the community and how laxatives are used by community-dwelling adults. Because OTC laxatives are widely available without prescription, it is not clear which laxative agents are being used, why and how they are selected, and for what purpose they are used. OTC laxatives are intended for use in the management of constipation although they are sometimes used by consumers for other purposes such as weight loss [12]. In managing constipation, OTC laxatives may be used in two ways—either for treatment or for prevention of constipation [13]. Treatment of constipation refers to the use of a laxative to relieve constipation symptoms. Prevention of constipation refers to use of a laxative to prevent the symptoms of constipation from occurring. In the context of constipation management, it is also important to understand consumer satisfaction regarding OTC laxative effectiveness [14]. Although laxatives feature prominently in constipation management, rigorous scientific evidence for their efficacy is scarce because most OTC laxatives have been in use for several decades [15]. Nevertheless, therapeutic outcomes of OTC laxative usage in the community are not necessarily reflected in clinical trials [16].

## 2. Prevalence of Laxative Use

There are a number of possible explanations for the wide range of results in studies estimating the prevalence of laxative use. Firstly, any differences in prevalence between countries might be explained by the same factors as differences in prevalence of constipation, i.e., differences in culture, diet, environment and genetics may be partly responsible [8]. For laxatives in particular, socioeconomic differences and differences in healthcare systems may be important considerations as they may impact the availability and affordability of laxative products in different countries. Particular aspects of healthcare systems which may differ between countries include differences in product availability with and without prescription, and differences in product reimbursement.

It is difficult to compare prevalence when different studies have used different study designs. One research group has conducted multinational studies in 11 countries using the same methodology and questionnaire [18][19]. In each country, the sample size was 2000 subjects, aged 15 years or older and representative of the country's population (except China where the sample size was 2100 and subjects aged over 60 years were excluded). Using the same sample size and data collection method in each country should ensure consistent data and enable comparisons between countries. However,

because the term "laxative" was not defined and no list of laxative products was provided, the legitimacy of such comparisons is weakened. Nevertheless, calculation of the prevalence of laxative use in the community shows that prevalence ranged from 16% in Korea to 40% in USA and Indonesia.

Within one country, it might be expected that the prevalence of laxative use would fall within a narrow range, but this has not been the case in the studies reviewed. For example, two Canadian studies have reported different prevalence rates. In a phone survey of 1149 adults with self-reported constipation over three months [36], 34.3% had used laxatives (laxatives were not defined other than the use of prescribed or OTC medication for constipation during the past three months). However, in another Canadian survey 86.5% of 200 participants self-reporting constipation over the last 12 months had used some form of laxative products which included herbal or homeopathic products, fibre and foods [37]. This disparity illustrates that vastly different results may be obtained from the same country when different survey methods, different sample sizes, different constipation definitions, different time periods and no standard laxative definitions are used.

Differences in study design will influence prevalence results. For example, various data collection methods have been used in studies, the most common being face-to face (FTF) interviews. Similar to constipation prevalence studies [8], the research method used may influence survey results. Because of participant embarrassment, FTF interviews may result in lower prevalence rates compared to mail or internet surveys. For example, in North America [18][36][38] and Europe [14][18][29] internet surveys have reported prevalence rates that were up to twice those of surveys conducted by FTF or phone interviews. Another aspect of study design relates to the sample. As with constipation prevalence [8], the sample size may affect the prevalence of laxative use. Study samples have ranged in size from 200 [37] to 72,000 [33] participants. Because sample size calculations have usually not been provided, it is not clear if the chosen sample sizes are appropriate. It is also not clear in most surveys if the sample used was nationally representative; in over half of the studies, regional populations were surveyed. Nationally representative samples are preferred for estimation of prevalence, along with some evidence of representativeness. Similar to constipation prevalence [8], the age range of the sample is another important consideration. In most studies of the general adult population, participants sampled were at least 15 or 18 years old with no upper limit but in some studies [5][21][22][23][31][32][33][39][44], the age of participants was restricted, therefore not all adults in the community were included.

Unfortunately, the majority of studies have not provided definitions of the term "laxative" which means it was self-defined by survey participants. One study of adults with chronic constipation [14] defined the term precisely and included a product list to aid recall; the prevalence was 30% or more higher than most other comparable studies where the meaning was self-defined [22][23][29][36][42][45].

Provision of a product list not only aids definition but also improves recall by providing a useful memory aid [47]. If not defined, it is possible that participants may not regard products such as bulk-forming laxatives and herbal products as laxatives. Also, in some studies where laxatives have not been precisely defined, certain products such as bulk-forming (fibre) products have been either specifically included [22][31][38] or excluded [39]. The ATC laxative definition (A06A: Drugs for constipation) is an international drug classification system, that could be used as a standard definition [11]. The ATC definition includes all OTC laxative agents including bulk-forming laxatives and herbal laxatives, oral and rectal forms, as well as prescription laxatives. In studies reporting the prevalence of laxative use in constipated populations, the definition of constipation is an important consideration as this will also influence the result [8]. Differentiation is usually made between chronic and any constipation. For chronic constipation, most studies used one of the Rome criteria definitions. The majority of studies have reported laxative use with only one definition of constipation.

The recall period used in surveys is an important consideration when estimating prevalence of laxative use [47]. Most studies did not specify any time period. Yet, some studies enquired about current laxative use [9][14][38], and others defined a time period for laxative use such as the past two weeks [27][28], one month [21][26], 3 months [36] or 12 months [18][19][22][23][29][33][37][40]. Clearly the recall period should be defined, and different recall periods will influence the estimated prevalence of laxative usage [47]. Whenever information is elicited from participants, a potential for recall bias exists.

## 3. Laxative Choice, Utilisation and Satisfaction

Laxative choice varied by country. In North America, stool softeners such as docusate were popular despite a lack of evidence regarding efficacy [48][49][50], and prescription products feature prominently in US studies [9][38], possibly because more new products have been approved there than elsewhere. An important consideration with laxative choice is the year in which the study was conducted. Many studies were over ten years old and older studies may be less relevant because of changes in product preference and availability. For example, the increasing world-wide use of macrogol as an OTC osmotic laxative and the recent availability of new prescription laxatives in some countries need to be considered [51].

Most adults attempt self-management in the first instance [9][37]. In most cases, healthcare professionals are not consulted [29][36][52] and importantly, healthcare professionals are usually not involved with OTC laxative product selection [20][53]. It has been postulated that this might be the result of advertising and other media as well as the possibility of patient embarrassment in discussing constipation [54]. Consequently, OTC laxative choice and use may not always be appropriate [20]. Without advice from healthcare professionals, appropriate product selection and directions for use are challenging for the consumer [53] who may be influenced by other less reliable sources of information [20] such as advertising, acquaintances, or relatives.

High levels of dissatisfaction with laxatives have been reported mainly because of poor efficacy with no differences noted in laxative classes. This may be related to how laxatives are being used. Daily use of laxatives indicates use for prevention rather than treatment. Another indication of preventive use is that some adults report laxative use but not constipation. It seems clear that there is a dual purpose for laxative use—prevention and treatment of constipation, apart from any use not related to constipation. However, no studies have investigated this aspect. In particular, no studies have assessed the perceived effectiveness of laxative agents used for treatment compared to those used for prevention of constipation. Appropriate OTC laxative choice for the intended purpose should be based on the onset of action [55]. The high levels of dissatisfied laxative users in several studies suggest that laxatives are not being used appropriately [9][14][37] [38]. Knowledge of the effectiveness of laxatives in practice is essential for improving the management of constipation in the community.

## 4. Limitations

A limitation of the literature review is the risk of bias, whereby the studies included were conducted in an English-speaking context and written in English and were further refined according to the inclusion/exclusion criteria. The risk of bias is acknowledged since some relevant studies may have been excluded from the literature reviewed. The authors also acknowledge potential recall bias because survey results were based on recall of participants, the period of which varied in different studies. Furthermore, differences in healthcare systems in different countries will also influence the results obtained in different studies.

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