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EVALUATION OF CONSTIPATION MANAGEMENT IN THE LEBANESE COMMUNITY PHARMACIES

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Abstract: *Objective:* The aim of the study was to evaluate the practice of constipation management by Lebanese pharmacists. *Methods:* This was a population-based observational study conducted in 120 community pharmacies distributed across Lebanon. The study population comprised patients who seek the community pharmacy asking for a self-selected or prescribed medications for the treatment of constipation and who were willing to complete a structured questionnaire. *Results:* A total of 2290 patients who had constipation and willing to complete the questionnaire were included. Overall, hard stools and infrequency of less than 3 times per week were the two most common constipation symptoms experienced by 73.5% and 70.4% respectively. Assessing the management of constipation, few were the patients who tried non-pharmacologic and complementary therapies (14.6%, 3.7% respectively). Nearly 80% of the patients received pharmacological treatment. Laxatives and combination therapy were more frequently used in chronic constipation compared to acute constipation (72.4 % and 71.5 % p-value < 0.05). *Conclusion:* Most participants needed counseling about the appropriate pharmacologic and non-pharmacologic management of constipation, and could benefit from such guidance in increasing their awareness related to laxative products, and possible combinations.

Keywords: Constipation; Complementary therapies; Community pharmacies; Laxatives

Introduction: Constipation is a widely common non-communicable condition. It can significantly affect daily living and well-being of the patients because it is a mentally and physically troublesome condition ¹. It is one of

the most common illnesses seen by gastroenterologists ², the fourth ranked cause of gastrointestinal disorders consultations ³. Constipation is defined as an unsatisfactory defecation characterized by infrequent stools, difficult stool passage or both ⁴. Female gender, increasing age, educational level and socio-economic status increase the prevalence of constipation. A small proportion of patients seek medical care, whereas most of the constipated population uses over the counter remedies to improve their condition ¹.

The management of constipation comprises of non-pharmacological, pharmacological and complementary therapy to achieve and maintain regular bowel movements free of symptoms⁶. The non-pharmacological therapy includes life style modification as physical activity and bowel training, diet modifications by increasing fluid and fiber intake ⁷.

The pharmacological therapy includes laxatives such as bulk forming laxatives, stool softeners, osmotic and saline laxatives, stimulant laxatives, and lubricants, as well as the prokinetics agents^{8,9}. Complementary therapy includes olive oil, flaxseed oil, tincture of jalapa, and the probiotics ^{10,11,12}.

Numerous prescription and over the counter laxative products are available in the community pharmacies, and millions of dollars are annually spent on laxatives alone, however only few patients report satisfaction with treatment ^{13,14}. The quality of life measurements and the well-being of the patients with constipation are reduced compared to control healthy subjects ¹⁵. In Lebanon, very few data exists concerning constipation management. Thus, the study was conducted to evaluate constipation management in the Lebanese community pharmacies.

Materials and Methods

Study Design

Evaluation of constipation management was a population-based observational cross-sectional study, conducted across community pharmacies distributed across Lebanon. This study was done over a period of 1 year from September 2014 till September 2015 in 120 community pharmacies. The study received ethical approval from the Institutional Review Board at the Lebanese International University, School of Pharmacy. An oral informed consent was taken from all participants enrolled in this study. The coding of the questionnaires after the completion of the survey ensured confidentiality and anonymity while entering the data.

Study Population

Patient's eligible if they are residing in Lebanon, self-selected or requested specific medicinal products or a prescription filling for treatment of constipation. Regularly/frequently constipated (according to their own definition or based on physician diagnosis) or have been regularly/frequently constipated and who are using, or who have used a laxative. Reasons for exclusion were pregnant female or not willing to fill the questionnaire. All study participants were given a self-administered, structured questionnaire to be filled. If the patient is a pediatric with a parent or a geriatric with a caregiver, the parent or the caregiver where asked to fill the survey on the behalf of the patient. If the patient doesn't read, the pharmacy student helped in the collection of data. The sample size calculation showed a minimum of 400 participants in order to be representative based on similar research tackling a common condition in Lebanon, with a confidence interval of 95% and a response rate of 50%.

Study Protocol

A standard questionnaire was used for documentation (Appendix 1). Each questionnaire included three distinct sections covering patients' characteristics, constipation description, and constipation management. For the patients' characteristics, each questionnaire was filled with patients' gender, age, socioeconomic status, frequent travelers.

In the part of constipation description, it was based on both patient and Rome III criteria. Rome III criteria Rome III criteria defines constipation as the presence of 2 or more of the following symptoms, straining, hard stools, incomplete evacuation, anorectal obstruction, manual maneuver, and fewer than 3 stools per week, for at least 3 months¹⁶. Management of constipation included nonpharmacologic, pharmacologic, and/or complementary treatment, where the use of laxatives was defined as any pharmaceutical intervention for management of symptoms; nonpharmacological management was defined as any lifestyle changes including hydration (increase fluid intake), diet (fibers) or exercise; complementary therapy was defined as the use of herbal products or pre/probiotics; and combination therapy is the use of more than one type of the management mentioned before.

Study Outcomes

The primary endpoint was to describe the criteria of constipation experienced by the patients and associate it with Rome III tool. The secondary endpoints were to assess the treatment modalities that the patients are using, including pharmacologic, non-pharmacologic and complementary remedies, and associate management options with age category, gender and type of constipation.

Statistical Analysis

Statistical analyses were conducted using Software Package for Social Sciences (SPSS) version 20.0. All questionnaires were coded for data handling and analysis, and tables were developed for frequency and percentage. Categorical differences were tested by chi-squared statistics and contributions of demographic factors to symptoms were assessed using a multiple regression model. Frequencies and percentages were used for categorical variables. Chi-square and fisher exact test were used for the associations and comparisons. Statistical significance was set at 0.05 using two-tailed tests.

Results

A total of 2290 participants were included in the study. More women (N=1329, 58%) were suffering from constipation. The majority of the respondents for this descriptive study belong to age group between 18 and 50. The percentage of having constipation was increased with increasing age. The age distribution of this sample consisted of 3.3% aged 0-12 years, 4% aged 12-18 years, 67.9% aged 18-50 and 24.8% aged more than 50 years. 37.5% of the participants had acute constipation whereas 62.5% had chronic type. 34.8% of the patients have a family history of constipation and 22.4% are frequent travelers. 39.9% have comorbidities, 39.2% are on treatment for comorbidities and 59.9% are on a drug that causes constipation as a side effect. Slightly more than half of the patients belong to a good socio-economic status (Table 1).

Table 1. Patients' Demographic Characteristics.

	N	(%)
Age		
0 – 12	76	(3.3)
12 – 18	91	(4)

18 – 50	1556 (67.9)
> 50	567 (24.8)
Gender	
Male	961 (42)
Female	1329 (58)
Classification	
Acute	858 (37.5)
Chronic	1432 (62.5)
Family history	797 (34.8)
Economic status	
Poor (< 500 \$)	261 (11.4)
Average (500 to 1500\$)	1310 (57.2)
Good > 1500 \$	719 (31.4)
Frequent travelers	
No	1778 (77.6)
Yes	512 (22.4)
Co-morbidities	
No	1377 (60.1)
Yes	913 (39.9)
Treatment of co-morbidities	
No	1391 (60.8)
Yes	897 (39.2)
Medication causing constipation	
No	919 (40.1)
Yes	1371 (59.9)

Constipation Symptoms

Overall, hard stools and fewer than 3 bowel movements were the two most common constipation symptoms experienced by 73.5 and 70.4 percent of all eligible participants respectively. Straining, sensation of incomplete evacuation and inability to defecate were experienced by 68.3, 57.8 and 54.9 percent of eligible participants respectively. Manual maneuvers to facilitate at least some defecation were the least experienced symptoms by

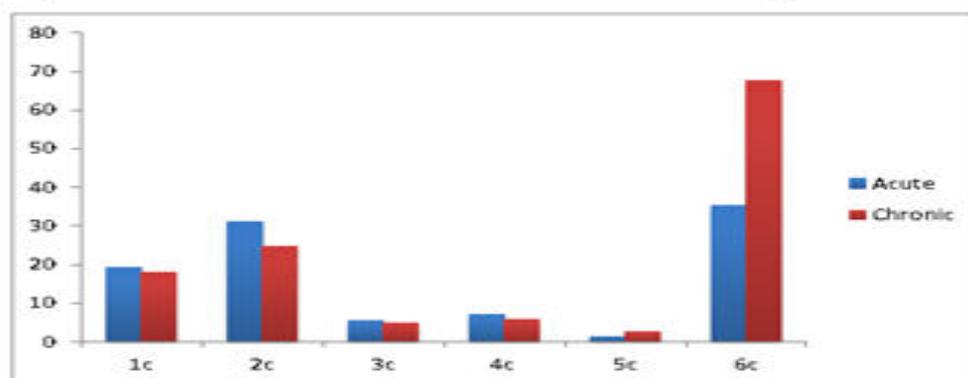
only 43.5% of all participants. On average, about two-third of the patients experienced constipation symptoms for more than 3 months and were classified as chronic and 37.5 percent of the patients' experienced acute constipation. 40.7% of the patients enrolled experienced all the 6 criteria of constipation together, followed by 27.2% of patients experiencing 2 criteria at once (Table 2).

Table 2. Criteria of Constipation.

Criteria for constipation	N	(%)
Straining	1565	(68.3)
Hard stool	1683	(73.5)
Inability to defecate	1258	(54.9)
<3 stools/week	1613	(70.4)
Incomplete defecation	1323	(57.8)
Digital manipulation	997	(43.5)
Rome III criteria score		
1/6	423	(18.5)
2/6	622	(27.2)
3/6	117	(5.1)
4/6	147	(6.4)
5/6	48	(2.1)
6/6	933	(40.7)

The majority of patients in the acute and chronic groups were experiencing all the 6 criteria of constipation together, 35.3% and 67.5% respectively with p-value <0.0001 (Figure 1).

Figure 1: Rome III Criteria in Acute v/s Chronic constipation



Treatment of Constipation and Use of Laxatives

The most common action for managing constipation was the use of medical intervention, primarily use of laxatives, ranged around 70% among all participants and among different age groups. Nearly 10% of the patients used a combination of pharmacologic and nonpharmacologic treatment of constipation with more than one-third of the patients (37.6%) taking hyperosmotic laxatives for managing the condition. The second more commonly used laxatives were stimulant laxatives with 28.3 percent of the dispensed medications. The frequency of use of the different management of constipation was similar according to diagnostic criteria of acute and chronic constipation.

The majority, 52.3% of the patients were on hyperosmotic laxatives, followed by 39.3% on stimulants. Lubricants were the class that is the least used (0.2%) (Table 3).

Table 3. Management of Constipation.

Management of constipation	N	(%)
Pharmacologic treatment (Laxative use)	1645	(71.8)
Nonpharmacologic treatment	334	(14.6)
Complementary therapy	85	(3.7)
Combination therapy	226	(9.9)
Types of laxatives		
Bulk forming laxative	19	(1.2)
Hyperosmotic	861	(52.3)
Emollient	73	(4.4)
Lubricant	4	(0.2)
Saline	41	(2.5)
Stimulant	647	(39.3)

Association between Different Therapies among Acute and Chronic Constipation

The chronic constipation group used more hyperosmotic laxatives than stimulant laxatives compared to the acute constipation group. The use of the nonpharmacologic management was greater among the acute constipation group compared to the chronic constipation group (16.2 v/s 13.6% respectively with p-value = 0.019), while combination therapy was used more frequently in the chronic constipation group compared to the acute constipation group (11.2 v/s 7.6% respectively with p-value =0.009) (Table 4).

Table 4. Association between Different Therapies among Acute and Chronic Constipation.

	Acute N (%)	Chronic N (%)
Laxative use	621 (72.4)	1024 (71.5)
Bulk forming laxative	7 (1.1)	12 (1.2)
Hyperosmotic	300 (48.3)	561 (54.8)
Emollient	25 (4.0)	48 (4.7)
Lubricant	-	4 (0.4)
Saline	23 (3.7)	18 (1.8)
Stimulant	266 (42.8)	381 (37.2)
Combination	65 (7.6)	161 (11.2)
Complementary therapy	33 (3.8)	52 (3.6)
Non-pharmacologic management	139 (16.2)	195 (13.6)

Association between Different Therapies among the Age Groups

There was no consistent differences management of constipation among the different age groups, where laxative use was the highest, followed by the nonpharmacological management. Within laxative use, hyperosmotic laxative was the main therapy used in patients aged 0-12 years (80%), while the other groups, both hyperosmotic and stimulant laxatives were used ranging at approximately 50 and 40 percent respectively. A greater percent (78%) of participants aged more than 50 years reported to use laxatives compared with younger subjects (Table 5).

Table 5. Association between Different Therapies among the Age Groups.

	Age Groups			
	0 – 12 N (%)	12 – 18	18 – 50	> 50 N (%)
Laxative use	55 (72.4)	63 (69.2)	1085 (69.7)	442 (78.0)
Bulk forming Laxative	-	1 (1.6)	12 (1.1)	6 (1.4)
Hyperosmotic	44 (80.0)	34 (54.0)	559 (51.5)	224 (50.7)
Emollient	5 (9.1)	2 (3.2)	40 (3.7)	26 (5.9)
Lubricant	-	-	3 (0.3)	1 (0.2)
Saline	4 (7.3)	3 (4.8)	24 (2.2)	10 (2.3)
Stimulant	2 (3.6)	23 (36.5)	447 (41.2)	175 (39.6)
Combination therapy	4 (5.3)	4 (4.4)	165 (10.6)	53 (9.3)
Complementary therapy	2 (2.6)	3 (3.3)	59 (3.8)	21 (3.7)

Non-pharmacologic management	15 (19.7)	21 (23.1)	247 (15.9)	51 (9)
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Association between Different Therapies for Constipation Management among Gender

No consistent differences in the management of constipation and laxative use between genders. A greater percent of women compared to men (72.9 vs 71.0% p-value = 0.06) used laxatives, with women and men using more osmotic laxatives than stimulant ones. (48.8 and 55.0% p- value = 0.079 and 42.9 and 36.7% respectively p- value = 0.09) (Table 6).

Table 6. Association between Different Therapies for Constipation Management Among Gender.

	Gender	
	Men N (%)	Women N (%)
Laxative use	701 (72.9)	944 (71.0)
Bulk forming laxative	6 (0.6)	13 (1.4)
Hyperosmotic	342 (48.8)	519 (55.0)
Emollient	32 (4.6)	41 (4.3)
Lubricant	3 (0.4)	1 (0.1)
Saline	17 (2.4)	24 (2.5)
Stimulant	301 (42.9)	346 (36.7)
Combination	104 (10.8)	122 (9.2)
Complementary therapy	37 (3.9)	48 (3.6)
Non-pharmacologic management	119 (12.4)	215 (16.2)

Discussion

Appropriate assessment of constipation in the community is an important aspect of the condition treatment plan. Many studies conducted in the world have identified inadequate management of constipation due to the lack of definite guidelines and the abundance of therapeutic drug options¹⁷. Our study was conducted on 2290 participants from all regions of the country where appropriate constipation management was assessed, and a stepwise approach in the treatment of constipation is needed by the pharmacist.

Management of constipation depends on both non-pharmacological and pharmacological therapies, where conservative treatment is usually insufficient and should be supplemented with laxatives or motility enhancing drugs. It is necessary to increase intake of fibers to reduce colonic transit time and improve the frequency and consistency of stools in patients¹⁸. Moreover, the daily intakes of 2 liters of water enhance the positive effects of fibers. Although some controversy exists about the effectiveness of exercise in constipation treatment, encouraging as much aerobic exercise as possible alleviates symptoms and seems reasonable. Even walking may help stimulate bowel motility and, certainly, is unlikely to hurt most patients^{6,19}. With respect to laxative use, the choice among them is based upon costs, ease of use, patient preference, and results of response to empiric treatment. None of laxatives, enemas, and suppositories, really addresses the underlying problem. In a recent meta-analysis²⁰, the respective responses of osmotic laxatives and stimulant type versus placebo were: 61% v/s 31 %, and 58% v/s 22%. Those are evidence-based results, however the duration of use of laxatives, specifically stimulant type did not exceed the 4 weeks in the included trials. The disadvantages of those 2 classes are the side effects that range from abdominal distension, flatulence and even diarrhea.

Misdiagnoses of chronic constipation were common in patients presenting to purchase laxatives. Patient with acute versus chronic constipation were classified according to Rome III criteria which defines chronic constipation as the presence of 2 or more of the following symptoms, straining, hard stools, incomplete evacuation, anorectal obstruction, manual maneuver, and fewer than 3 stools per week, for at least 3 months. 18.5% of the patients had only one of the criteria and don't fit the diagnosis of chronic constipation¹⁶. But both acute and chronic patients were prescribed similar therapies. According to further statistical analysis there is a

significant association between therapies among acute and chronic constipation, p-value < 0.05. Patients with acute or chronic constipation were on laxatives, where hyperosmotic laxatives scored the highest percentage. Patients with chronic constipation tend to use a combination of products more than in acute constipation, the scenario sounds logical but the statistics did not make it significant in our study. A strong association is also shown in our results among the management of constipation in different age groups, 78% of the constipated population above 50 was on laxatives. Studies have shown that those results are comparable to all world results where laxatives are mostly used by the elderly population²¹. The increase of the use of laxatives in elderly was comparable between genders.

Our study showed a consisted data in gender differences to previous studies conducted, where Higgins et al²², and Irvine et al²³, have both demonstrated that the female population is at higher risk of having constipation compared to male. Moreover, Gonenne et al²⁴, stressed on the fact that hormonal differences between males and females may be the causative factor of a higher prevalence of constipation in the female population, but no significant association between laxative use and gender differences.

Despite this study being the only representative population-based surveys for constipation in Lebanon, some limitations do subsist. First, this study is cross-sectional by nature, so we may have an issue with temporality where it is not possible to conclude which preceded the other especially in secondary constipation, is it secondary type? Is the co-morbidity and drug for comorbidity and other conditions started before the onset of constipation? Cross-sectional studies do not establish causal relationship between exposure and outcome but originate hypothesis to be confirmed by stronger study designs. The use of questionnaires depends on the ability of the patient to recall symptoms. In addition, we could not assess the impact of the overuse or misuse of drug for constipation since we don't have their side effects. Patients' dependence on treatment couldn't be measured too, due to the lack of the section tackling these aspects in the survey.

Comorbidities would have been interesting if detailed in the survey, and the treatment of comorbidities is also important to know. Age categorization was not optimal; a solo category of more than 65 years of age would have given more significant results comparable to the global numbers. Pharmacist play important role in

management of constipation, thus evaluation of pharmacist knowledge is essential to improve the outcome on patients

Conclusion

Constipation is a common problem worldwide and affects up to 30 % of the general population. Only a minority of patients seek healthcare. Thus, the identification of the patients and the management of constipation are hard to track. The role of the pharmacist in the management of gastrointestinal problems specifically constipation is crucial. The patient is at high risk for becoming dependent on laxatives and developing a laxative colon, if he was not counseled regarding the appropriate dietary prophylaxis with follow-up visits.

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