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Original Research Article

The study to understand management of constipation and prescription pattern of laxative therapy

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ABSTRACT

Background: The objective of this study was to evaluate demographic profile and prescription pattern of laxative therapy in chronic constipation (CC) patients.
Methods: This real-world, retrospective, SMART-2 study was conducted at various centres in India between April 2021 and March 2022.
Results: Data of a total 12,080 patients diagnosed with CC were analysed. The mean age of patients was 53.84 years and majority (63.62%) were males. Most reported influencing lifestyle parameters included 'not very active' or 'lightly active' lifestyle (78%) and non-vegetarian diet (67%). Squatting (56.89%) was the common mode of defecation. As per the Bristol stool criteria, the most common stool consistency observed was type 2 (sausage-shaped but lumpy) (25.49%) followed by type 1 [separate hard lumps, like nuts (hard to pass)] (22.92%). As per the Rome IV diagnostic criteria, straining (44.62%) was the most common symptom. Faecal evacuation disorder was present in 52% of the patients. Common associated conditions were diabetes (35%) and hypothyroidism (12.9%). Antihypertensive drugs (23.7%), iron supplements (13.5%) and opiates (10.7%) were the most commonly prescribed drugs in patient's medication history. Lactulose solution (65%) was the most prescribed drug for CC. Quality of life was adversely impacted in every one out of five patients.
Conclusions: Chronic constipation is more common among males and is influenced by lifestyle parameters. It is associated with comorbidities like diabetes and hypothyroidism. Antihypertensives, iron supplements and opiates are commonly noted in medication history for CC patients. Lactulose solution is the most common prescribed pharmacotherapy for the relief from constipation. Chronic constipation increases distress level among the patients.

Keywords: Chronic constipation, Lactulose, Comorbidities, Distress

INTRODUCTION

Chronic constipation (CC) is one of the commonly diagnosed conditions in gastroenterology practice and a major healthcare burden affecting quality of life of the patients. The prevalence of CC is 2-27% worldwide.[1] It is characterized by difficult, infrequent, and/or incomplete defecation.[2] CC is common in the elderly, and is present in every one of five adults aged >65 years.[3] It is observed frequently in females than in males and in nonworking population than in working population.[4] The common symptoms of CC include infrequent bowel movements (<3 per week), hard stools, sensation of incomplete evacuation, abdominal distress, bloating, distention, excessive straining, anorectal blockage and need for manual manoeuvres during defecation.[5] Although CC is typically managed using over-the-counter medications at home or in an out-patient setting, serious and immediate life-threatening etiologies may be responsible for this presentation and diagnosing these etiologies seems imperative.[6] Several factors are widely thought to be

associated with constipation, however, real-world evidence of these associations is difficult to locate.[7] The potential associated risks include demographic, lifestyle and health-related factors.[8,9] In the community, the primary risk factors include low exercise levels, low fibre intake and inadequate fluid intake.[10] Besides, risk factors, many other pathologies are also associated with CC.[11] In the diagnosis of constipation, a thorough evaluation of the symptoms is warranted to accurately diagnose the disease.[12] The ROME IV criteria is the most commonly used criteria to diagnose CC.[2] The overall diagnosis of CC requires an evaluation of predefined symptoms and the ROME criteria, hence, a medical interview with patients assists in confirming the diagnosis.[2,12]

CC can be managed with massage, physical exercise, defecation habits, increased fluid intake, acupuncture, pharmacological agents, surgical approach and faecal microbiota transplantation.[12,13] The pharmacological treatment options for CC include use of laxatives, secretagogues, serotoninergic agonists, and probiotics and prebiotics.[12] Laxatives are among the mostly used agents in CC. Of note, osmotic laxatives are considered the first-line therapy in the treatment of CC.[2,13] Lactulose, an osmotic laxative, is amongst the most used pharmacological agents. Lactulose is a semi-synthetic disaccharide derived from isomerized lactose, and has been used in the treatment of CC.[14] According to the World Health Organization (WHO), lactulose is listed as an essential medicine, available as powder, oral solution and enema formulations.[15] Despite medical treatment, patients with CC suffer from diminished quality of life due to the physical symptoms and psychological distress of CC, and have a reduced work productivity and social interactions.[12]

The study was conducted to determine the demographic patterns in patients with CC in India and the prescription pattern of laxative therapy among them.

METHODS

Study design

This real-world, retrospective, cross sectional, observational SMART-2 study (The Study to understand Management of Constipation And PrescRiption pattern of Laxative Therapy) was conducted at various centres including hospitals, clinics, and health care institutes in India between April 2021 and March 2022. The study inclusion criteria were patients with CC who were prescribed laxative therapy at study centers in India.

Study variables

Patients were selected based on treating physician's discretion, and no additional evaluation or investigations were performed during data capture. The demographic variables included age, gender, level of physical activity, and the type of toilet used. Disease related variables included for the evaluation were co-morbidities, diagnostic criteria, type of stool based on Bristol scale severity of symptoms as per ROME IV criteria, symptoms suggestive of faecal evacuation disorder, management approach, medications prescribed, and the quality of life.[16,17]

Statistical analysis

There was no formal sample size calculation in this real-world study, and only the patients' data were collected retrospectively. The study did not assess any hypothesis and only the observations from patient's records were analyzed. The data was collected from all centers across India and appropriate statistical analysis was performed at Lambda Therapeutics Limited Ahmedabad, India.

Demographic and baseline characteristics were summarized using descriptive statistics. Categorical variables were summarized with frequency and percentage. Continuous variables were summarized with count, mean, standard deviation, etc. Graphical presentation of data was done using pie chart/bar chart as appropriate. Statistical analyses were performed using SAS® Version 9.4 (SAS Institute Inc. USA).

Ethics statement

The study was conducted after due approval from Om Institutional Ethics Committee, Ahmedabad, India. This was a retrospective study without patient identifiers; hence, the informed consent of patients was not taken. There was no confidentiality breach of the data during its analysis and interpretation.

RESULTS

Data of total of 12,080 patients who were diagnosed with CC at various centres across India between April 2021 and March 2022 were evaluated. Table 1 provides the demographic details of patients in this study. The patients had a mean age of 53.84 years. When gender distribution was assessed, majority of the patients were males (63.73%) while females constituted 36.27% of the population. The physical activity distribution showed that majority of the patients were 'not very active' (34.22%) or 'lightly active' (43.88%). Most of the patients were non-vegetarians (67.19%). Use of Indian toilet was reported for 56.89% of the patients while 43.11% patients were using western toilet. A recent change in toilet type from Western to Indian toilet was reported in only 6.07% patients whereas shift from Indian to western toilet was reported in 17.73% patients.

Type of stool consistency in patients with CC as per Bristol stool criteria

Among the study cohort, type 2 (sausage-shaped but lumpy) stool consistency was the most common type (25.49%) followed by type 1 [separate hard lumps, like nuts (hard to pass); 22.92%] (Figure 1).

Symptoms as per Rome IV criteria

As per Rome IV criteria, straining during >25% of defecations occurred in 44.62% patients followed by lumpy or hard stools in >25% defecations, which occurred in 39.64% patients. Sensation of incomplete evacuation for >25% of defecations was faced by 29.33% patients (Figure 2).

Symptoms suggestive of faecal evacuation disorder

Mild, moderate, and severe CC were reported in 36%, 56.47%, and 7.52% patients. In patients with mild CC, prolonged (>30 min) and excessive straining was the most common symptom (64.8%) while in patients with moderate CC, infrequent defecation (<3 per week) was most common symptom. Patients with severe CC had prolonged (>30 min) and excessive straining as the most common symptom (41.58%). In patients with severe CC, manual evacuation with a need of perineal and vaginal pressure to assist defecation was observed in 22.44% patients, which was more common as compared with patients having mild (7.01%) or moderate (6.24%) CC (Figure 3).

Type of CC as per colon transit time

Normal-transit CC was the most common type of CC (36.95%; n=4464) followed by slow-transit CC (52.80%; n=6378) and pelvic floor dysfunction (3.80%; n=460). Details related to transit time or pelvic floor dysfunction were not available for 6.44% patients (n=778).

Common associated disease conditions and medication history

When enquired about comorbidities which might be the potential cause of CC, diabetes (35.8%) was reported to be the most common associated condition followed by hypothyroidism (12.9%), anal fissure (9.3%), inflammatory bowel disease (7.2%), haemorrhoids (5.6%), anal strictures (3.9%), Parkinson's disease (3.8%) and proctitis (1.5%) (Figure 4). The medication history of these patients revealed that anti-hypertensive drugs were most commonly (23.37%) used by them followed by iron preparations (13.05%), opiates (10.7%), tricyclic antidepressants (5.27%), anti-epileptic drugs (3.72%) and anti-parkinsonian drugs (2.69%). Almost half (47.07%) of the patients did not report use of any previous medication.

Prescribed drug therapy

Lactulose oral solution (64.59%) was the most prescribed agent with majority of the patients being prescribed lactulose oral solution as monotherapy (54.59%). The other common medications prescribed were ispaghula husk powder (22.41%), lactitol (12.44%), PEG oral solution (11.37%) and prucalopride (4.51%) (Figure 5).

In patients receiving lactulose oral solution, the most common dosage frequency was once daily (OD, 59.9%) followed by twice daily (36.3%) and thrice daily (4.84%); data related to dosage frequency was not available for remaining 1.7% patients.

Table 1: Patient characteristics.

Parameters	All patients (n=12,080)
Age (years), mean	53.84
Gender, N (%)*	
Men	7685 (63.73)
Women	4373 (36.27)
Physical activity status, N (%)	
Not very active	4134 (34.22)
Lightly active	5301 (43.88)
Active	2310 (19.12)
Very active	335 (2.77)
Dietary habit, N (%)	
Non-vegetarian	8117 (67.19)
Vegetarian	3963 (32.81)
Toilet type, N (%)	
Western	5208 (43.11)
Indian	6872 (56.89)
Any recent change in toilet type, N (%)	
Western to Indian	734 (6.07)
Indian to Western	2142 (17.73)
None	9204 (76.19)

*- Data available for 12058 patients. Type 1: Separate hard lumps, like nuts (hard to pass); type 2: sausage- shaped but lumpy; type 3: like a sausage but with cracks on the surface; type 4: like a sausage or snake, smooth and soft; type 5: soft blobs with clear-cut edges; type 6: fluffy pieces with ragged edges, a mushy stool; type 7: watery, no solid pieces, entirely liquid.

Table 2: Impact of CC on quality of life (distress subscale).

Parameters	Never	Rarely	Occasional	Usually	Always
	N (%)	N (%)	N (%)	N (%)	N (%)
Discouraged that I am not getting better	4331 (35.85)	3169 (26.23)	3144 (26.03)	1051 (8.70)	385 (3.19)
Helpless in my ability to solve my bowel problems	2966 (24.55)	3885 (32.16)	3423 (28.34)	1416 (11.72)	390 (3.23)
Frustrated that the treatments I have tried do not work	3215 (26.61)	3086 (25.55)	3655 (30.26)	1600 (13.25)	524 (4.34)
Worried that this problem will not go away	3066 (25.38)	3336 (27.62)	3401 (28.15)	1770 (14.65)	507 (4.20)
Depressed that my bowel problems are controlling my life	3328 (27.55)	3242 (26.84)	3216 (26.62)	1628 (13.48)	666 (5.51)
Nervous that this means something more serious is happening to my body	3886 (32.17)	3110 (25.75)	3034 (25.12)	1403 (11.61)	647 (5.36)

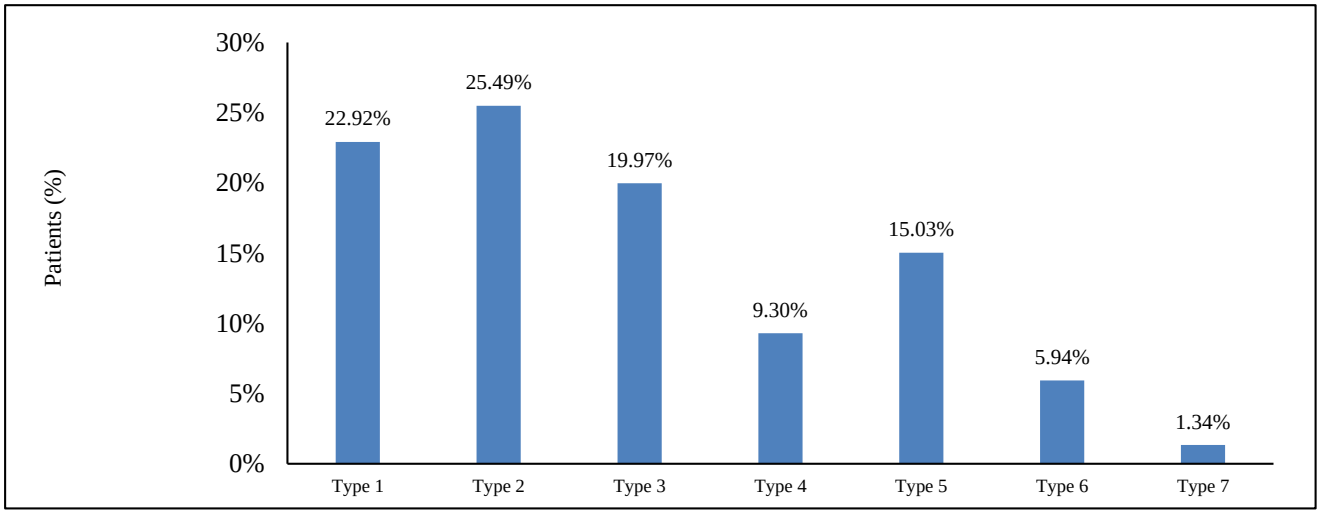

Figure 1: Type of stool consistency in patients with CC.

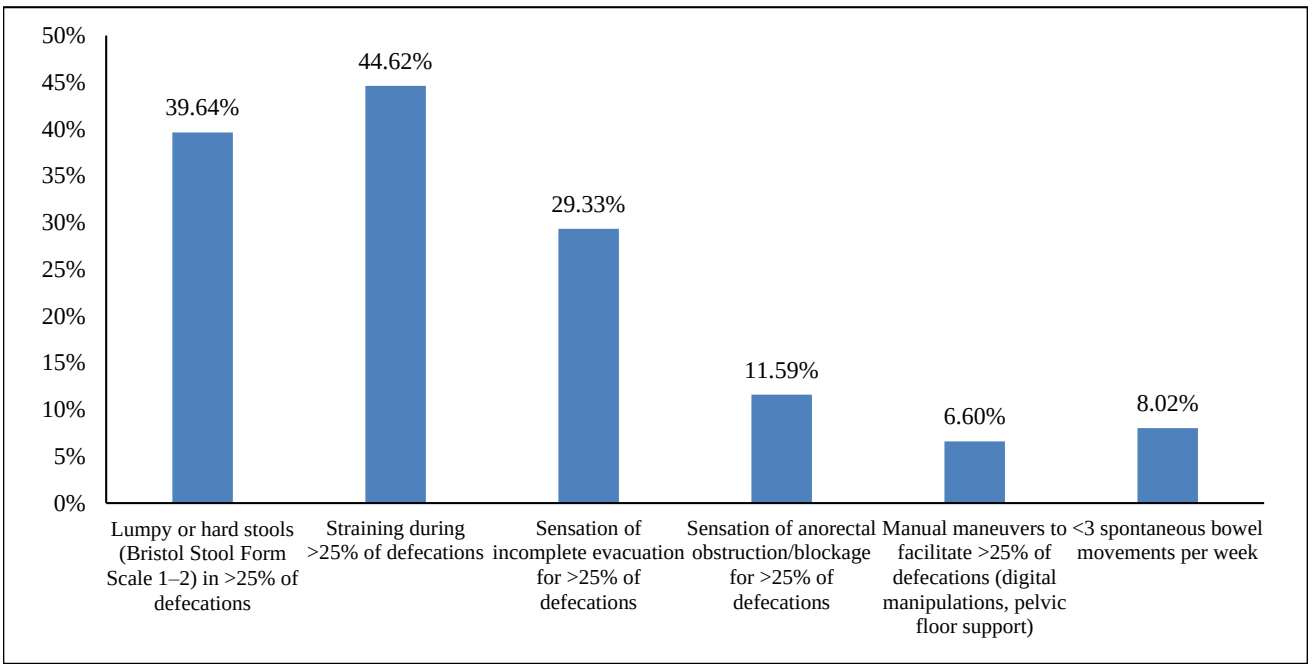

Figure 2: Symptom distribution as per Rome IV criteria in patients with CC.

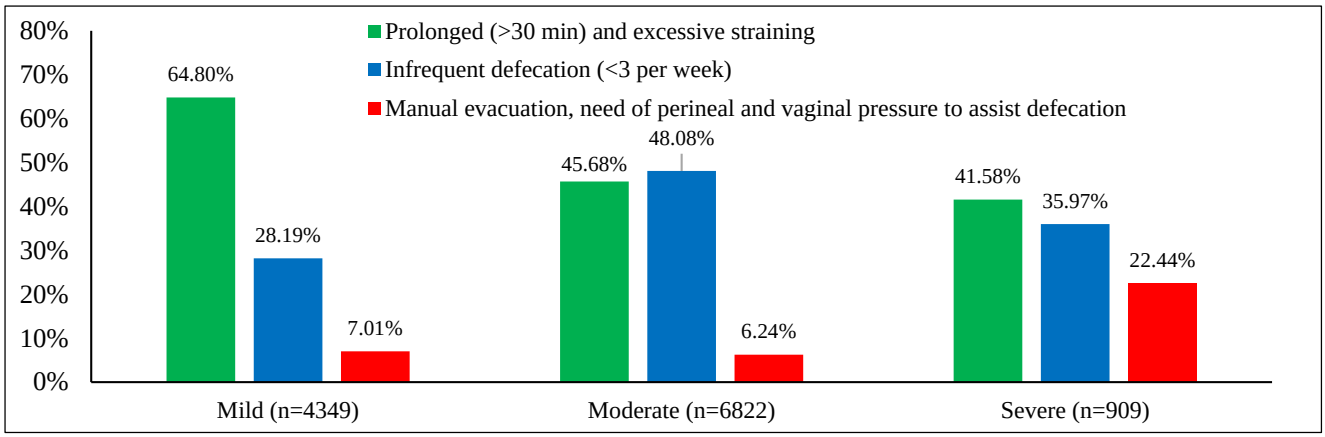

Figure 3: Symptoms suggestive of faecal evacuation disorder.

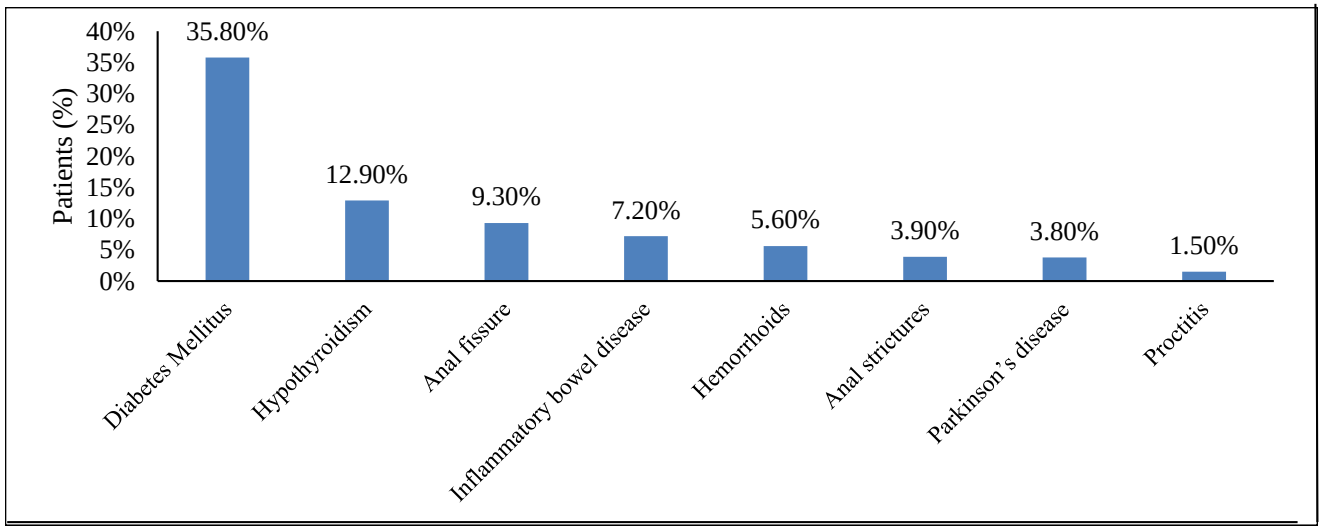

Figure 4: Common associated disease conditions.

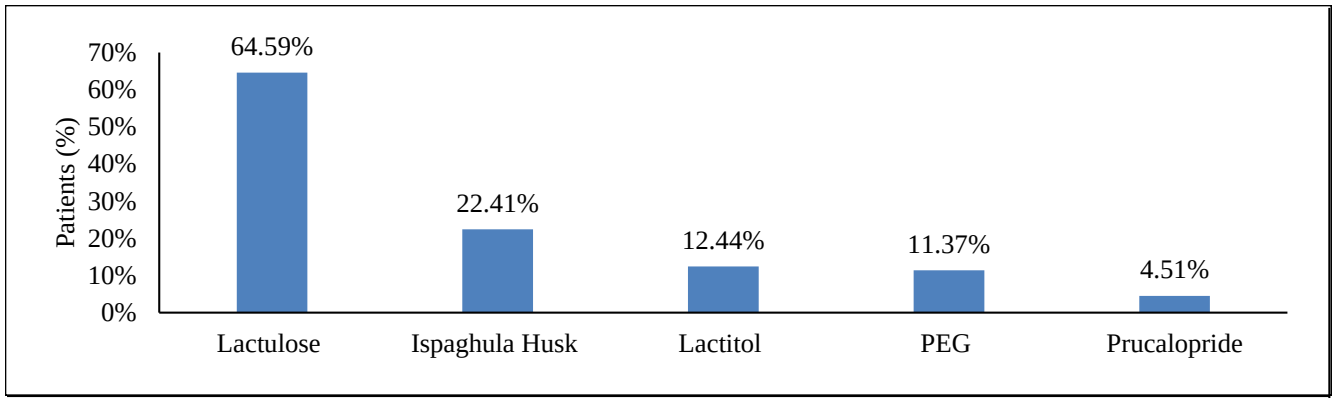

Figure 5: Common prescribed agents for CC.

Impact of CC on distress level

In the context of impact of CC on distress among patients, approximately 1 out of every 6 patients always or usually felt frustrated that the treatments he/she had tried did not work (Table 2).

DISCUSSION

CC is a common problem reported in Indian clinics.[18] The epidemiology, clinical spectrum, diagnostic assessment, treatment need, and expectations among patients with CC in India are somewhat different compared to the west.[4] The present real-world observational study evaluated data

related to demographic patterns, disease symptoms and prescription patterns among 12080 patients with CC who presented at various centres across India.

Various epidemiological surveys have reported that lifestyle factors including insufficient dietary fibre and fluid intake, sedentary life, prolonged bed rest, systemic illnesses, irregular and inadequate time in the toilet, and chronic consumption of drugs contribute to CC.[19,20] Majority **(**78%) of the patients in this study had sedentary or lightly active lifestyle and were non-vegetarians (67%). A recent multicentre study from India showed the association of physical inactivity, posture during defecation, smoking, intake of tea/coffee/alcohol, and animal protein intake with CC.[21] An Indian study conducted on eastern coast evaluated defecation frequency and predominant stool forms among 1200 apparently healthy subjects and found that non-vegetarianism, and sedentary lifestyle were associated with reduced defecation frequency.[22] Another community study from northern India found CC to be more in non-working people, non-vegetarians, and those with lesser fluid and green leafy vegetables/fruits/cereals intake, and poor physical activity.[23]

Defecatory postures differ according to culture; squatting and sitting are the most common defecation postures worldwide. Conventional Indian toilets require squatting posture, but more people are gradually switching to western style toilets in urban areas in India. As compared to sitting, squatting is more physiological, ideal, and a relaxed posture for defecation.[24,25] About more than half (56.89%) of the patients in current study used Indian type of toilet, relating to the squatting posture. Although, there is limited published literature supporting the advantages of squatting posture, a study from Israel comparing three postures during defecation (squatting, sitting on standard height toilet seat, and sitting on low height toilet seat) showed that both, the time needed for sensation of satisfactory bowel emptying, and the degree of subjectively assessed straining were much lower in those with squatting position as compared to other two sitting postures.[26] In a recent study from Japan comparing three postures during defecation (squatting, sitting, and sitting with the hip flexed at 60° by placement of the feet on a height-adjustable step) showed that basal abdominal pressure before defecation was lowest and recto-anal angle on defecation was widest with squatting as compared to both of the other sitting postures.[27] In the present study, 17.73% patients with constipation had a history of shifting to sitting position from squatting position.

According to the joint position statement of the Indian Motility and Functional Diseases Association and the Indian Society of Gastroenterology in India, CC should be defined by stool forms and patients' perception rather than by stool frequency.[4] The Bristol Stool Form Scale (BSFS), a frequently used measure in gastroenterology practice and research, categorizes stools into one of seven stool types ranging from type 1 (hard lumps) to type 7 (watery diarrhoea).[16] In the present study, according to the Bristol scale, the stool forms were mostly of type I-IV. Similar results were reported by another study which was conducted in south Indian cohort of 1407 CC patients.[28] Constipation-associated stools, defined as Bristol types I-III, increase diagnostic sensitivity of CC in India than types I-II, as defined in the western countries.[4] In the present study, the Rome IV based criteria, which is considered as the gold standard in diagnosis of constipation, was implemented, wherein straining was observed in 44.62% of patients, lumpy or hard stools were present in 39.64% of patients while sensation of incomplete evacuation was observed in 29.33% of study patients.[29] In patients with severe CC, manual evacuation with a need of perineal and vaginal pressure to assist defecation was observed in 22.44% patients, which was higher as compared with patients having mild (7.01%) or moderate (6.24%) CC. The incidence of faecal impaction increases with age and dramatically impairs the quality of life in the elderly.[30]

Common co-morbid diseases with CC include hypertension, diabetes mellitus, and dyspepsia.[31] A study from West Bengal reported that 61.5% patients with CC had associated systemic co-morbidities such as diabetes mellitus (17.6%), and hypothyroidism (10.5%).[32] In the present study, diabetes (35%) was the most common associated condition with CC while hypothyroidism was present in 12.9% of study patients. Use of antihypertensive drugs was one of the most common medication histories besides opiates (10.6%) tricyclic antidepressants (5.27%), iron supplements (13.05%) among study patients. Tally NJ has reported a list of drugs that carry a significant risk of CC; these drugs include antidepressants, antipsychotics, anticonvulsants, antispasmodics, antihistamines, opioid analgesics, diuretics, iron and calcium supplements, and aluminium antacids.[33] In patients with CC, laxatives are the first line of pharmacotherapy.[18]

Osmotic laxatives like lactulose and bulk forming ispaghula contain non-absorbable molecules, which increase the water content in the stool thus softening its consistency and increasing its volume. In the present study, lactulose (65%) solution was the most prescribed drug therapy followed by ispaghula (22.41%) for CC. Osmotic laxatives are preferred first-line treatment for constipation by most physicians. As compared to other osmotic laxatives, lactulose exerts its action through varied mechanisms, resulting in several pleiotropic benefits.

Although CC is rarely associated with life-threatening complications, its impact on quality of life is significant when compared with unaffected populations.[34] In the context of impact of CC on distress levels, approximately 1 out of every 6 patients always or usually felt frustrated that the treatments he/she had tried did not work. A systemic review on quality of life parameters in CC demonstrated a consistent effect of CC on mental, physical and emotional components of QoL.[34] The strength of present study was that it was conducted across the country

on a large patient pool, however, being a retrospective observational study poses some limitations on the findings.

CONCLUSION

CC affects both genders. Lifestyle factors like non-vegetarian diet, squatting and sedentary habits contribute to CC. Diabetes and hypothyroidism are the most common associated causes. Antihypertensives, iron supplements and opiates are most reported medications used by these patients. CC severely increases distress level among the patients. Lactulose solution is the most commonly prescribed medication for CC.

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Ethical approval: The study was approved by the Om Institutional Ethics Committee, Ahmedabad, India

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