TO STUDY & ANALYSE THE POSSIBILITIES OF LAUNCH OF NEW MOLECULE IN THE SPACE OF CONSTIPATION

Internship Report submitted to

The IIHMR University, Jaipur

for the partial fulfilment for the award of the degree of

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in

Pharmaceutical Management

by

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Constipation:

Constipation refers to a condition where an individual has difficulty passing stool or has infrequent bowel movements.

Acute constipation

Chronic constipation

Slow transit constipation

Functional constipation

Medication-induced constipation

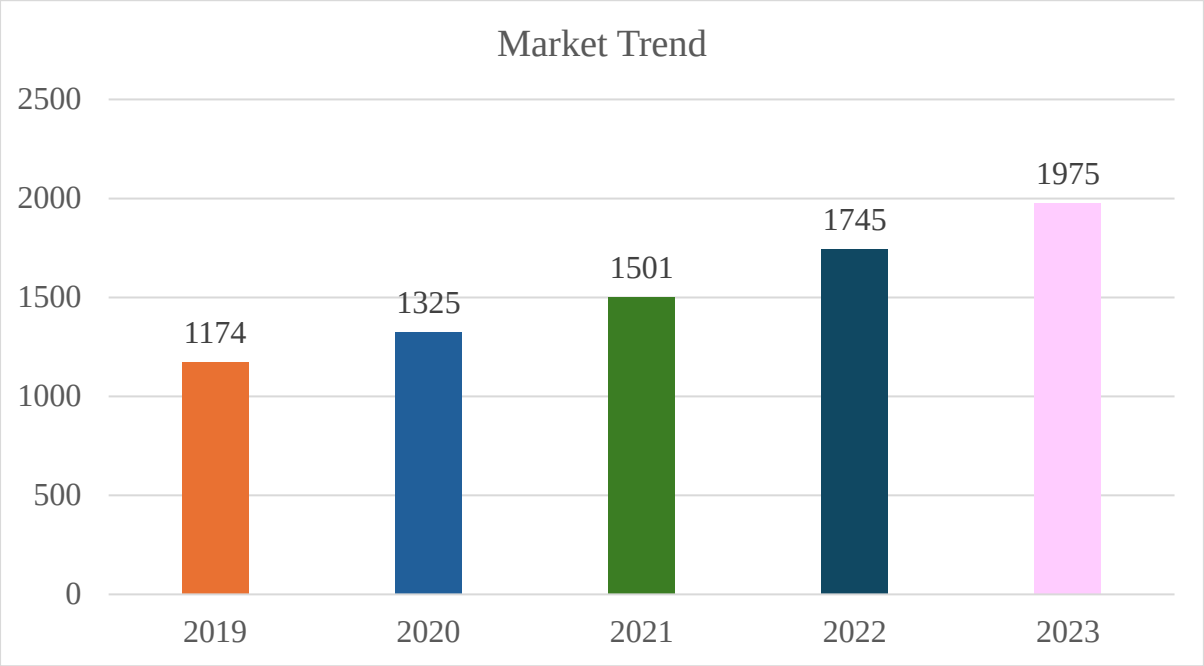
Classification of drugs use in constipation:

Classification	MOA	Examples
Bulk-forming laxatives	Increase stool bulk by absorbing water	Bran, psyllium husk, Ispaghula, methylcellulose
Osmotic laxatives	Draws water into the colon	polyethylene glycol, lactulose, or magnesium hydroxide
Stimulant laxatives	Promote bowel movements by stimulating the intestinal muscles	senna or bisacodyl
Stool softeners	Medications help to soften the stool by facilitating the absorption of water	Docusate sodium
Prokinetic agents	Improve intestinal motility and promote regular bowel movements	prucalopride, Lubiprostone

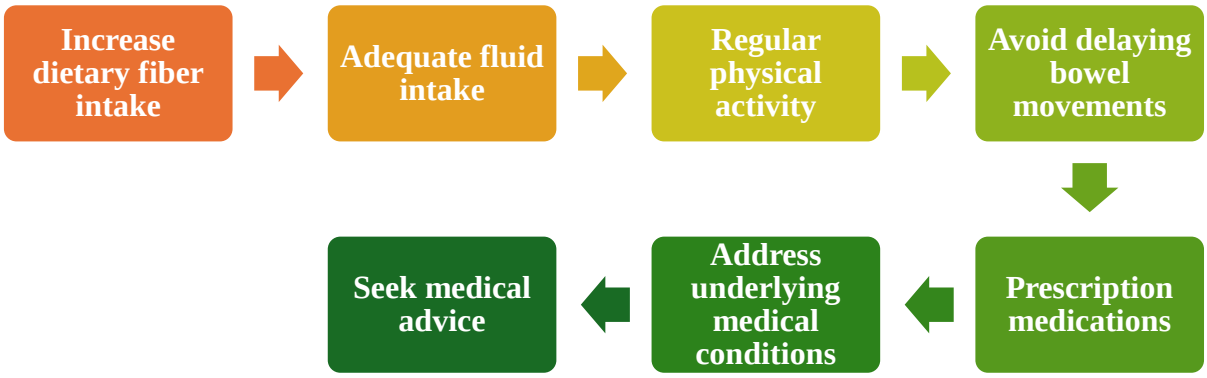
Chronic constipation:

- Chronic constipation refers to long-term or persistent constipation that lasts for an extended period, typically at least for **three months**. It is characterized by infrequent bowel movements, difficulty passing stool, or a feeling of incomplete evacuation.
- One of the main symptoms of constipation is having fewer bowel movements than usual. This may mean passing stool less than three times a week.
- Market size of constipation is about 2000 Cr.

CAGR of market is 14%



Management of Constipation:



Survey on Chronic Idiopathic Constipation

Name of the Doctor: -

Date: -

1. In your opinion, what is the prevalence of Chronic constipation in your patient population?
   - ☐ Less than 10%
   - ☐ 10% - 20%
   - ☐ 20% - 30%
   - ☐ More than 30%

2. What is the most common cause of chronic constipation in your patients?
   - ☐ Dietary factors (e.g., low fibre intake)
   - ☐ lack of physical activity
   - ☐ Medications (e.g., opioid painkillers, certain antidepressants)
   - ☐ Underlying medical conditions (e.g., irritable bowel syndrome, hypothyroidism)

3. Which therapeutic interventions do you typically recommend as the first-line treatment for patients with chronic constipation?
   - ☐ Fibre supplements (e.g., Ispaghula)
   - ☐ Osmotic laxatives (e.g., polyethylene glycol)
   - ☐ Stimulant laxatives (e.g., bisacodyl)
   - ☐ Prokinetic agents (e.g., prucalopride)
   - ☐ Other (please specify)

4. What is your preferred dosage form while prescribing laxatives?
   - ☐ Powder
   - ☐ Sachet
   - ☐ Liquid
   - ☐ Tablet

5. In your practice, what percentage of patients with chronic idiopathic constipation have not responded to first-line treatment option?
   - ☐ 0 - 5%
   - ☐ 6 - 10%
   - ☐ 11-15%
   - ☐ More than 15%

6. When initial treatment options for chronic constipation fail to produce satisfactory results, what is your preferred approach for second-line treatment?
   - ☐ Switching to a different class of laxatives
   - ☐ Adjusting the dosage or frequency of current medications
   - ☐ Adding a combination therapy of different laxatives
   - ☐ Other (please specify)

7. Are there specific medications or laxatives that you commonly prescribe as second-line treatment for chronic constipation?
   - ☐ Lubiprostone
   - ☐ Prucalopride
   - ☐ Other (please specify)

8. Where would you place prucalopride in the treatment of chronic constipation?
   - ☐ Slow transit constipation
   - ☐ IBS – C
   - ☐ Other (please specify)

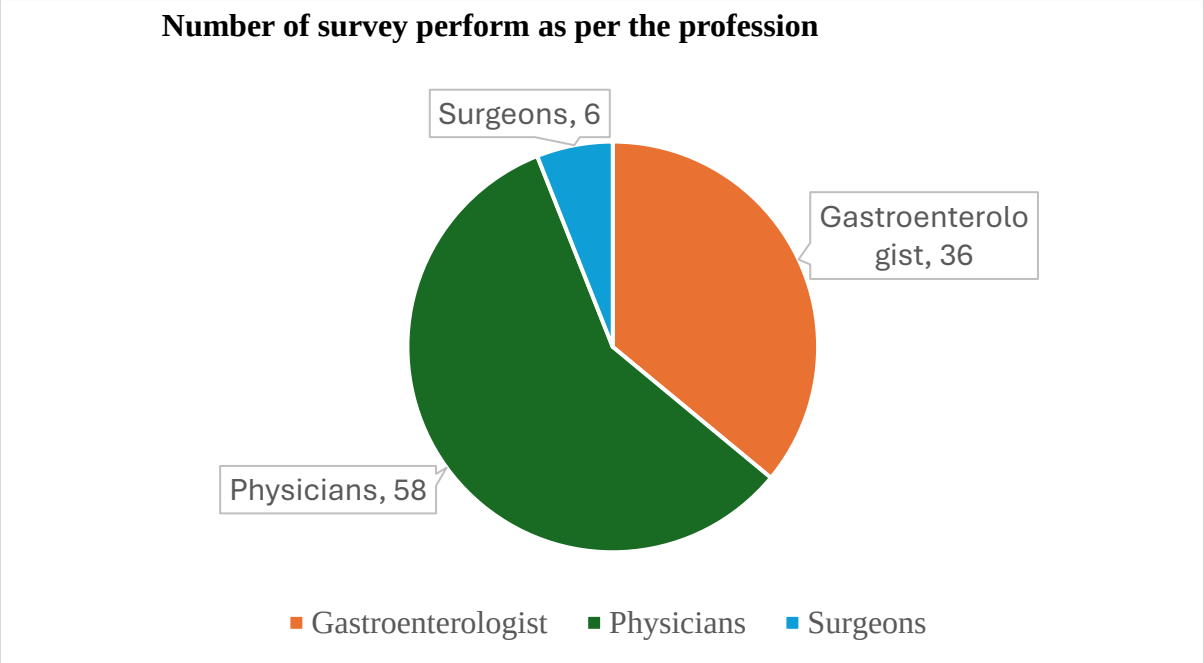
9. Have you heard about the molecule Plecanatide for the treatment of chronic constipation?
   - ☐ Yes
   - ☐ No

10. If yes, how familiar are you with the mechanism of action of Plecanatide?
    - ☐ Very familiar
    - ☐ Somewhat familiar
    - ☐ Not familiar

11. Among the current set of drugs, which molecule would you prefer for the treatment of IBS – C?
    - ☐ Prucalopride
    - ☐ Lactulose
    - ☐ Polyethylene Glycol
    - ☐ Lubiprostone
    - ☐ Other (please specify)

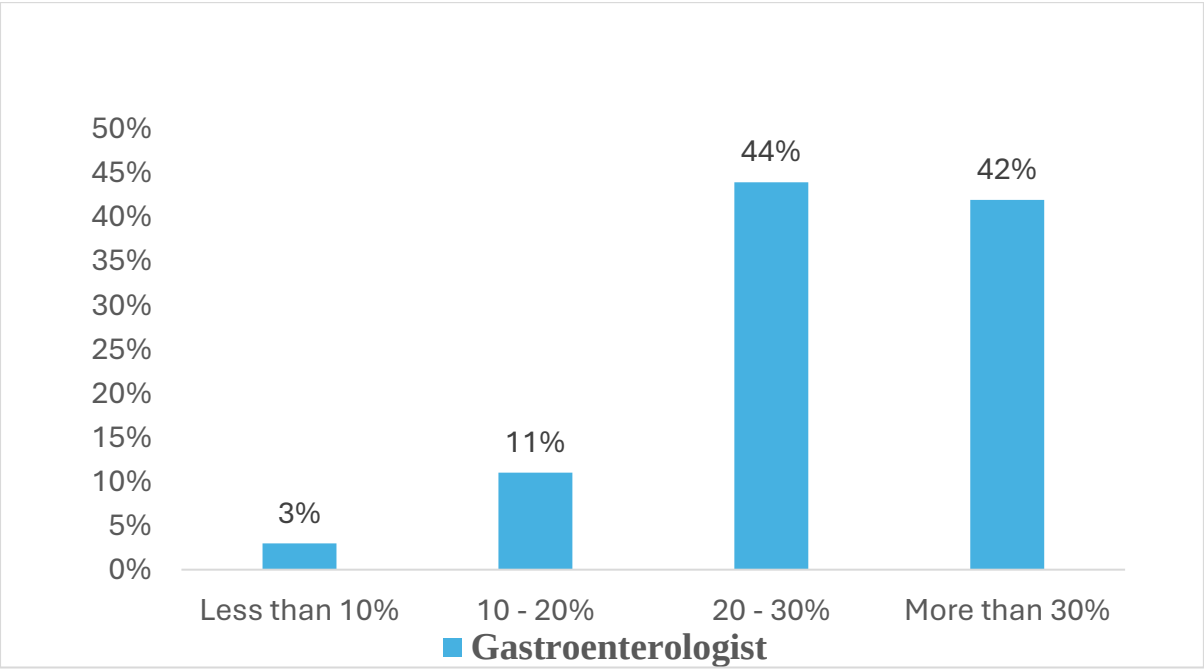
Signature: -

Stamp: -

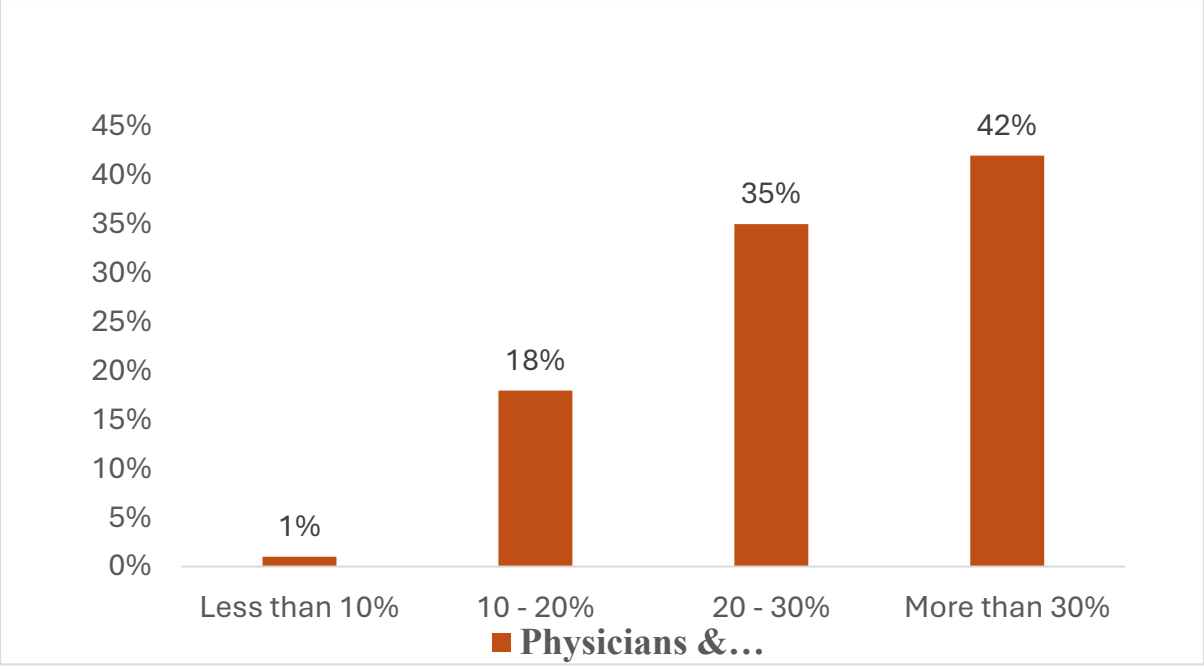


Analysis of Survey :

1. **In your opinion, what is the prevalence of Chronic constipation in your patient population?**

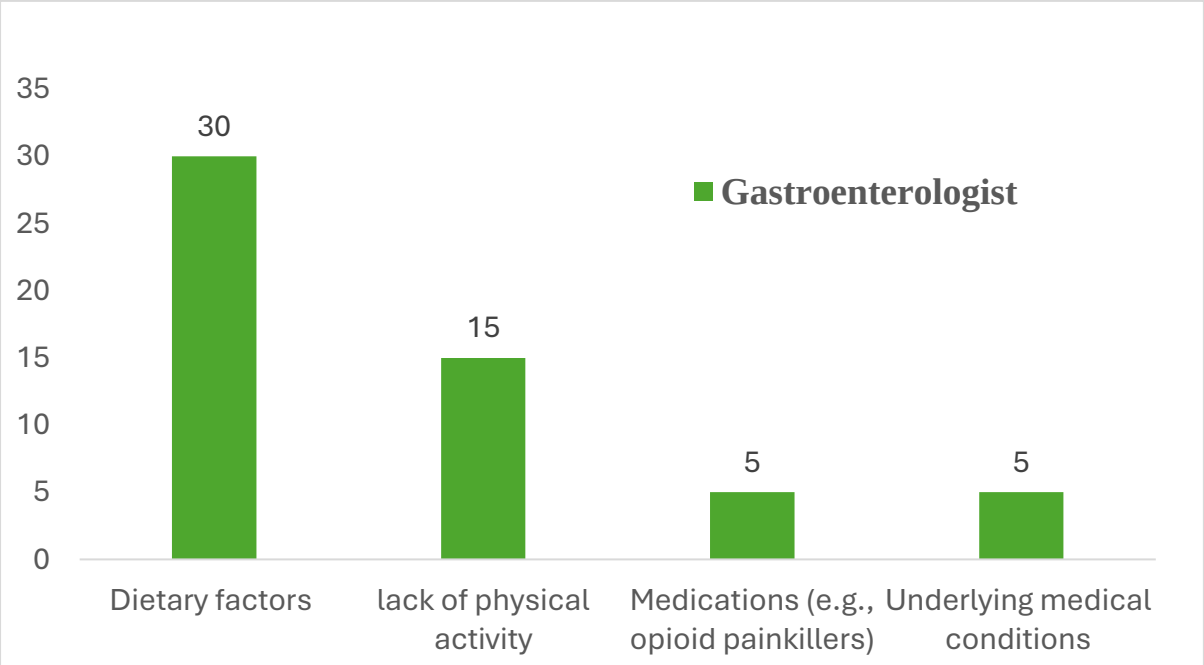


In gastroenterologist, the prevalence of chronic constipation in their patient is more than 20-30% of their patient population.

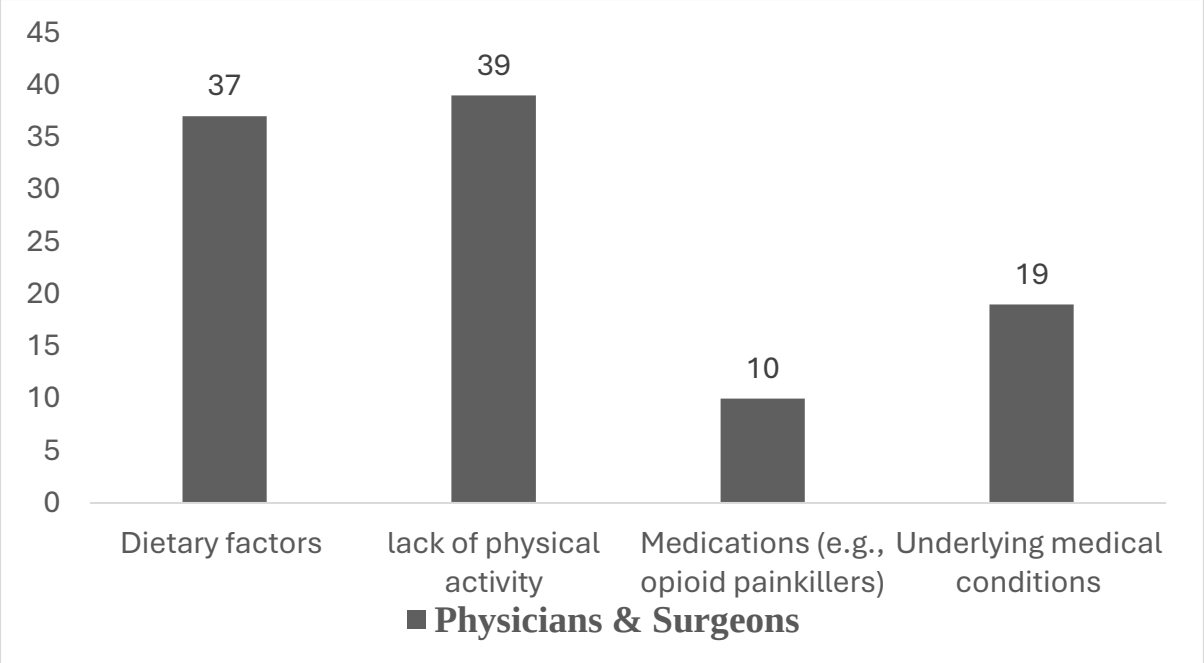


In Physicians & Surgeons, the prevalence of chronic constipation in their patient is more than 30% of their patient population.

2. What is the most common cause of chronic constipation in your patients?

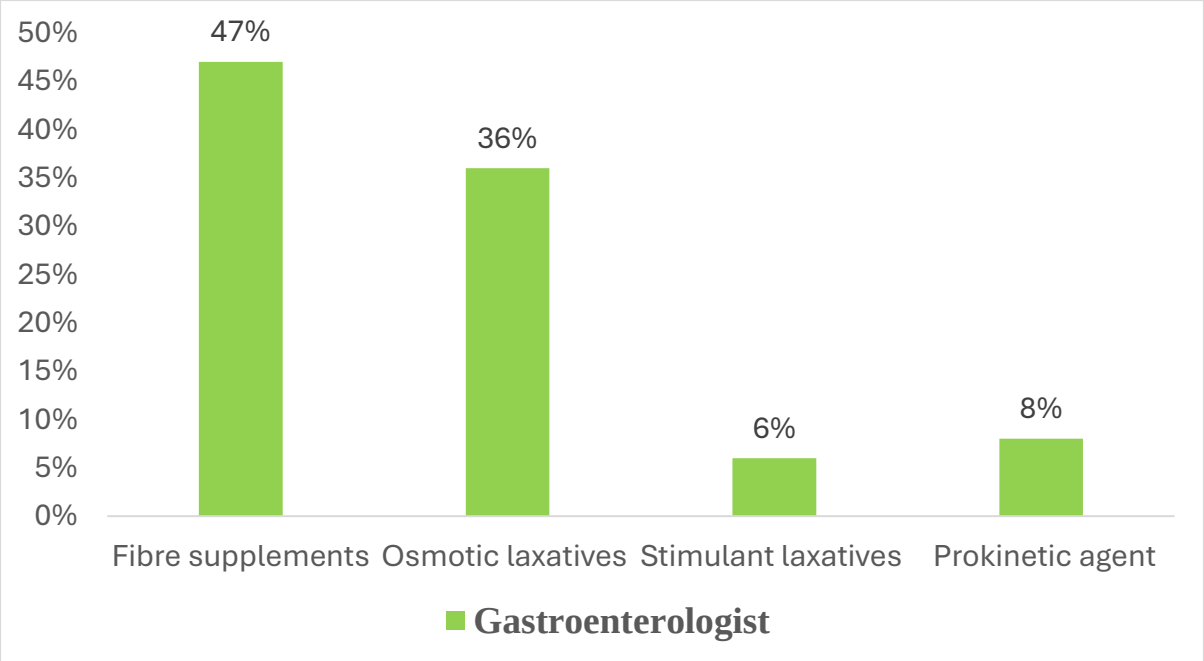


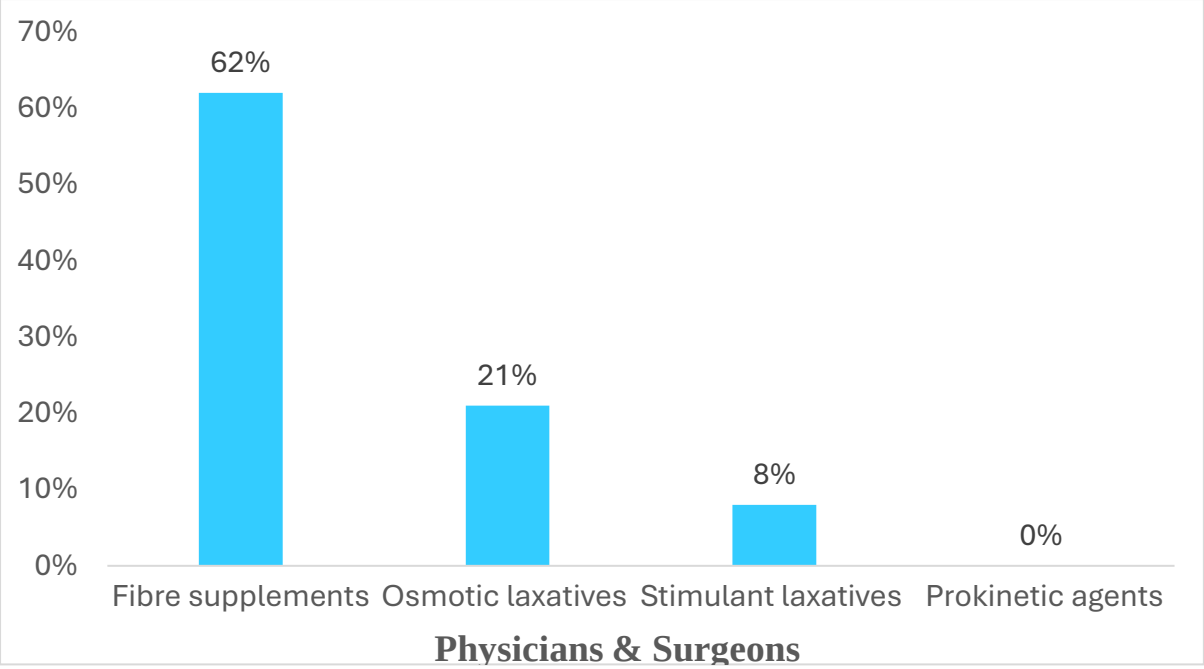
Common cause of chronic constipation is dietary factor followed with lack of physical activity in the patient of gastroenterologist.



Common cause of chronic constipation is lack of physical activity followed with dietary factor in the patient of Physicians & Surgeons.

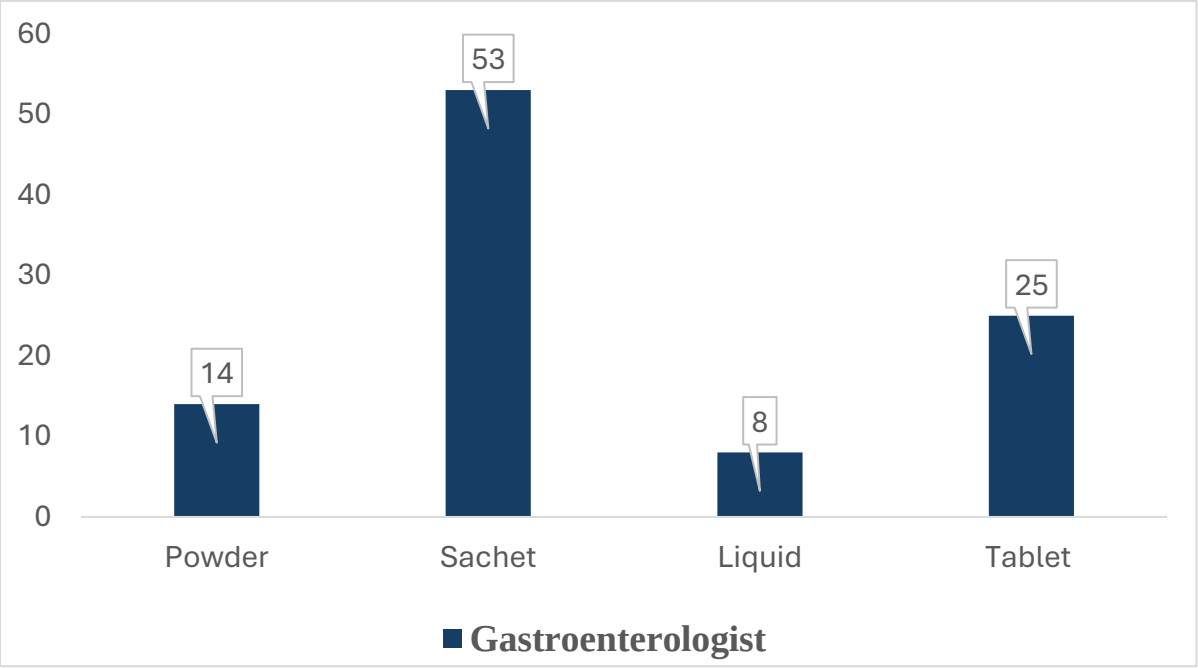
3. Which therapeutic interventions do you typically recommend as the first-line treatment for patients with chronic constipation?

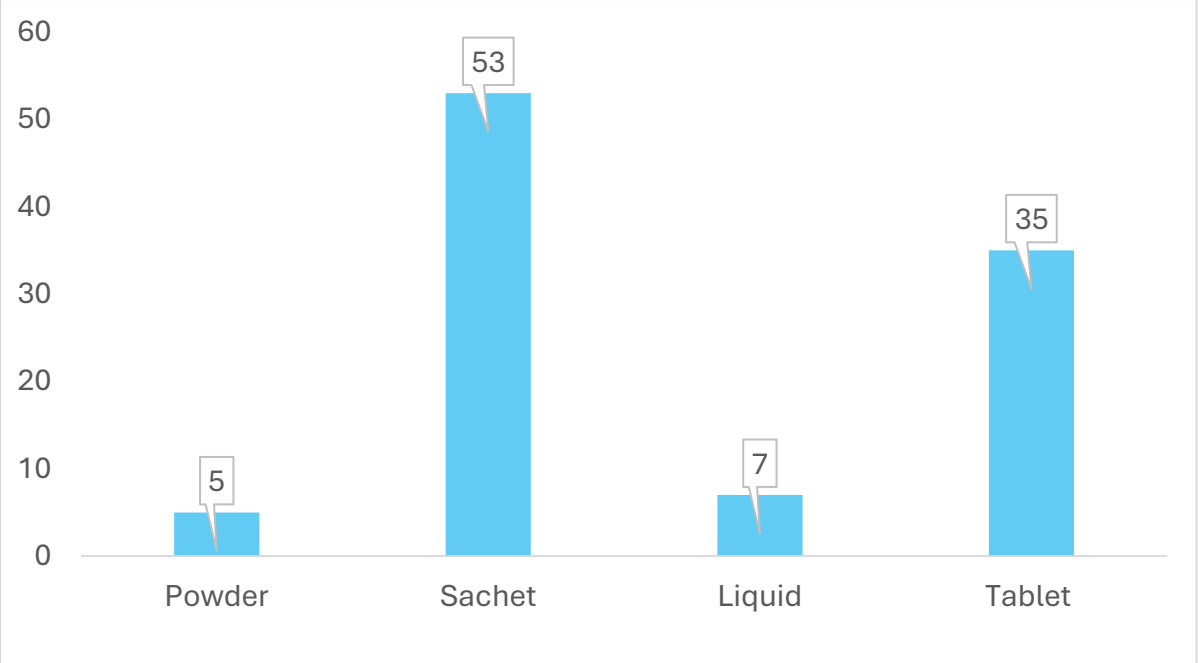




Depending on the cause of the patient the first line treatment is selected, if the cause is low dietary fibre, then the preferred treatment is fibre supplements and if the cause varies than the most commonly use first line treatment is osmotic laxatives according to the gastroenterologist.

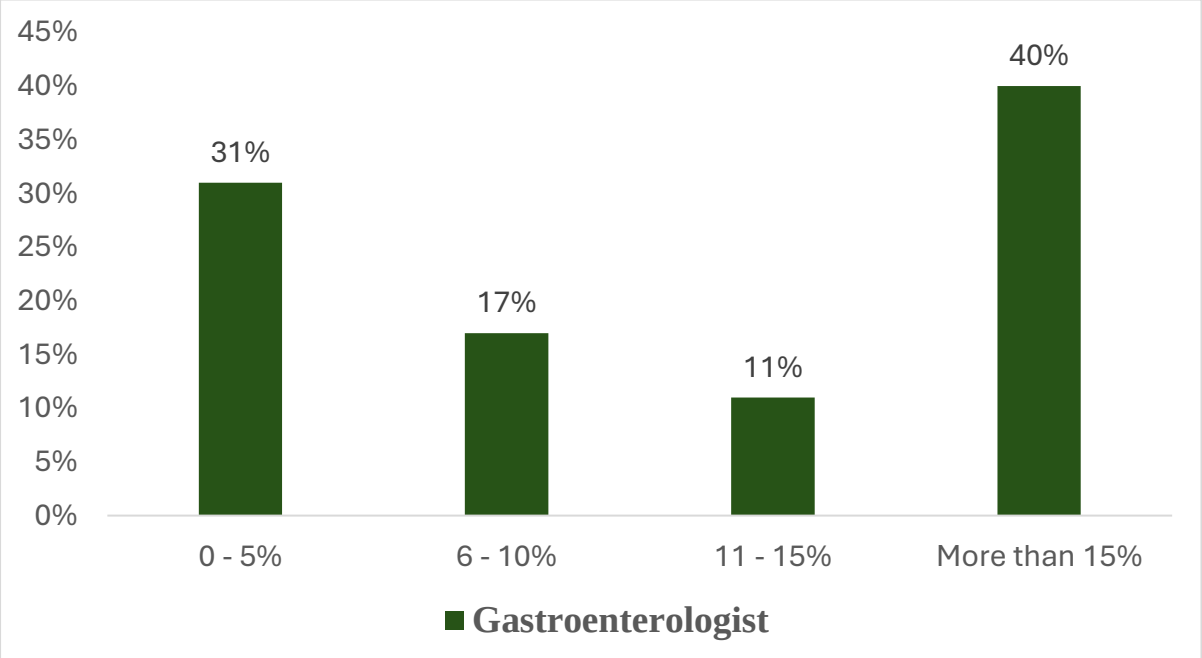
4. What is your preferred dosage form while prescribing laxatives?



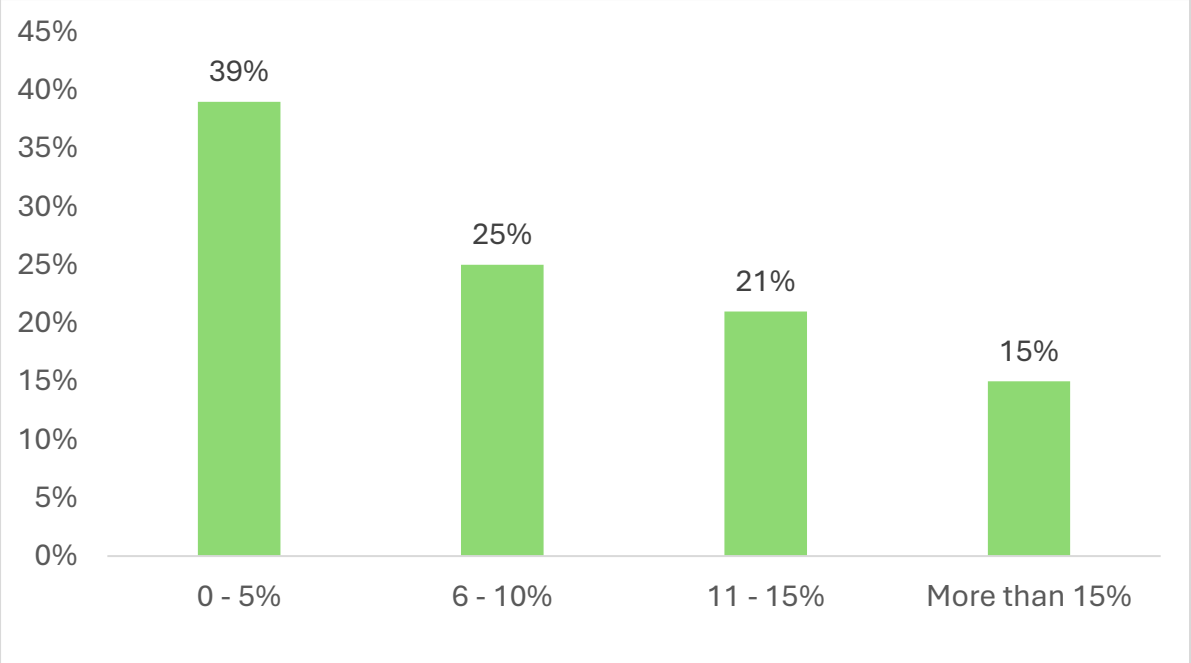


Most of the doctors preferred sachet as a dosage form while prescribing laxatives the reason for the same is noted that laxatives in the form can dissolve quickly in the gastrointestinal tract.

5. In your practice, what percentage of patients with chronic idiopathic constipation have not responded to first-line treatment option?

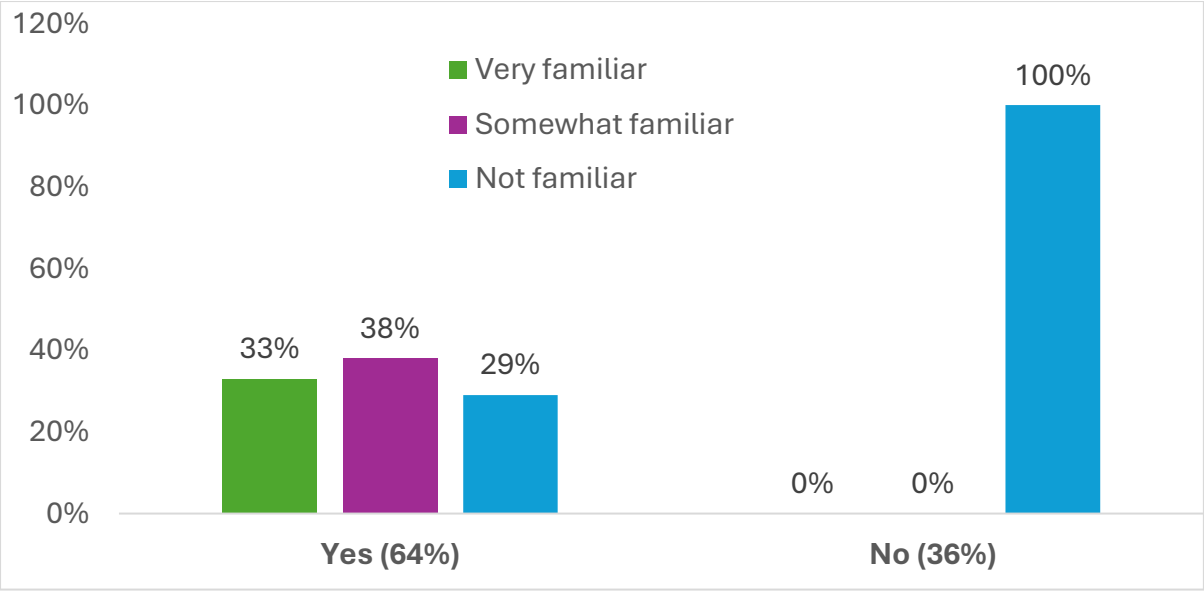


More than 15% patients visited Gastroenterologist who did not response to first line treatment and therefore requires second line treatment



Very less patient population does not response to the first line treatment who visited physicians & surgeons

Comparative Graph of Gastroenterologist:



10. How familiar are you with the mechanism of action of Plecanatide?

9. Have you heard about the molecule Plecanatide for the treatment of chronic constipation?

More than 60 % of the gastroenterologist are aware about the molecule and are somewhat familiar or are very familiar with its mechanism of action

Key points:

- There are more than 30% of patient population who deals with chronic constipation & most common cause among them are found to be is dietary factor & lack of physical activity in the patients.
- Treatment depends on the cause & if they fails to respond on the particular treatment, doctors modify the treatment either by switching to the different class of the laxatives which are preferred by physicians or by adding a combination therapy of different laxatives where most of the gastroenterologist prefers.
- In second line treatment, most of the doctors uses prucalopride and is highly rated as slow transit constipation molecule & is also used in IBS-C, which is in form of tablet, it is used when other laxatives are not working
- 70% of the doctors are aware about the molecule plecanatide but they are not familiar with its mechanism of action, or they are somewhat familiar with it.
- PEG & Prucalopride is used in the treatment of IBS-C by most of the physicians & gastroenterologists.

Suggestion:

1. Awareness Campaign:

Since most doctors are familiar with Plecanatide molecule but not of its mechanism of action (MOA), it would be beneficial for the us to conduct an awareness campaign targeting healthcare professionals. This campaign can focus on educating doctors about the MOA of Plecanatide and its benefits in the treatment of chronic constipation.

- ❑ CME (continues medical education) can be arranged
- ❑ Since plecanatide is use in U.S. as brand name – Trulance - 3 mg (FDA Approved 2018) use in CIC & IBS-C. There can be a seminar by experience doctors who has been using the molecule in the prescription in US which can give a clear idea of plecanatide.

2. Comparative Studies :

- Conducting comparative studies between Prucalopride and Plecanatide to demonstrate the advantages and efficacy of Plecanatide as a second-line treatment for chronic constipation, also highlighting unique properties or advantages of Plecanatide that differentiate it from other medications in its class.
- According to the clinical studies have shown that prucalopride increases bowel movement frequency and improves stool consistency in patients with chronic constipation.
- Whereas in plecanatide it results in increased intestinal fluid secretion and accelerated transit.

3.Providing Educational Material:

The materials will highlight the benefits, dosing instructions, potential side effects emphasizing Plecanatide as a suitable treatment option for chronic constipation.

- Creative pamphlets with description of plecanatide covering the points which shows no side effect
- Articles or studies by gastroenterologist who are familiar with the molecule
- Webinars or Live Q&A Sessions: Organize webinars or live question-and-answer sessions with experts where healthcare professionals and patients can learn more about the constipation molecule.
- Share relatable and inspiring stories of patients who have benefited from the molecule, where it is use.
- Produce short animated videos that explain how the constipation molecule works in the body
- Social media campaigns :- Produce short animated videos that explain how the constipation molecule works in the body

4. Patient Support Programs :

Establishing patient support programs that provide educational resources, lifestyle management tips to prevent from chronic constipation.

- Personalized counselling sessions with dieticians
- Lifestyle management tips by nutritionist
- Social media campaigns :- Adding multiple points of Do’s & Don'ts in constipation

Recommendation:

- Chronic constipation is a common condition that can significantly impact quality of life for affected individuals.
- In such cases, there may be a need for alternative treatment options that can provide relief and improve bowel function. Medications like plecanatide, which works by increasing fluid secretion in the intestines and promoting bowel movements, may offer an additional therapeutic option for individuals with chronic constipation who have not responded well to other treatments.
- Market size of constipation is 2000 Cr. Where very less molecules are being used as second line treatment
- Factors like cost is important while choosing between alternatives.