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Development of Personal Formulary for Constipation in Tertiary Care Settings

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ABSTRACT

Background: Constipation is one of the most common gastrointestinal disorders encountered in tertiary care settings and significantly affects quality of life across all age groups. Multiple classes of laxatives are available for treatment, including bulk-forming agents, stool softeners, osmotic purgatives, stimulant purgatives, and newer prokinetic agents. However, prescribing practices often vary due to clinician preference, availability, cost, and pharmaceutical promotion rather than objective comparison of efficacy, safety, convenience, and affordability. The concept of personal formulary (P-drug) development encourages rational and evidence-based selection of medicines.

Aim: To develop a personal formulary for constipation using the P-drug concept among residents of Pharmacology in a tertiary care setting.

Materials and Methods: This study was conducted in the Department of Pharmacology of a tertiary care teaching hospital. The P-drug for constipation in adults was selected using the WHO 6-step approach. Drugs from commonly used laxative groups available under the Janaushadhi scheme were evaluated, including Lactulose syrup, Lactitol and Ispaghula, Bisacodyl tablet, Liquid paraffin & Milk of Magnesia & Sodium Picosulphate suspension, Magnesium hydroxide & Aluminum hydroxide & Dimethicone tablet and Prucalopride tablet. Drugs were compared based on four parameters: efficacy, safety, cost, and convenience according to the P-drug concept of Joshi and Jayawick Ramarajah. Scores were given to each four parameters from 1 to 10 for each drug. Each parameter was given a fractional numerical rating (β) according to the importance i.e. 0.4 for efficacy, 0.3 for safety, 0.2 for cost and 0.1 for convenience. The total weighted score was calculated for each drug, and the highest-scoring drug was selected as the personal formulary drug.

Results: Among the evaluated drug groups, Osmotic purgatives achieved the highest score of 8.3 followed by bulk forming agents. Among the osmotic purgatives, Lactulose syrup achieved the highest total score (8.0), followed by Lactitol and Ispaghula combination (7.6) and Magnesium hydroxide & Aluminium Hydroxide & Dimethicone tablet. Though Ispaghula as a standalone formulation is not available in Janaushadhi, it's high safety and efficacy profile has influenced its comparison with Lactulose where it scored 8.3 but amongst the drugs available under Janaushadhi, Lactulose demonstrated good efficacy, favorable safety profile, reasonable

cost, and excellent convenience, making it the preferred P-drug for constipation.

Conclusion: By applying rational drug selection principles with greater emphasis on efficacy and safety, Lactulose syrup emerged as the most suitable personal formulary drug for constipation. The structured evaluation enhanced critical appraisal skills among residents and promoted safe, effective, convenient, and economical prescribing practices in routine clinical care.

Keywords: Constipation, P-drug, Lactulose, Rational drug use, Laxatives, Personal formulary.

INTRODUCTION

Constipation is a common gastrointestinal disorder characterized by infrequent bowel movements, difficult stool passage, excessive straining, hard stools, or a sensation of incomplete evacuation without any identifiable structural or biochemical cause.[1] According to the Rome IV criteria, the onset of symptoms must have occurred 6 months before diagnosis, and symptoms should include two or more of the following during the past 3 months: straining during excretion, stiff stools, feeling completely drained, after defecation manual maneuvers to facilitate bowel movements and less than three defecations during the week.[2] It is one of the most frequently encountered gastrointestinal complaints in both outpatient and inpatient practice and contributes substantially to impaired quality of life, reduced productivity, and increased healthcare expenditure.

Symptoms of constipation are reported by 10% to 20% of adults worldwide.[3] It has many reversible or secondary causes, including lack of dietary fiber, drugs, hormonal disturbances, neurogenic disorders, and systemic illnesses. In most cases of chronic constipation, no specific cause is found. Up to 60% of patients presenting with constipation have normal colonic transit.[4]

The pathophysiology of constipation is multifactorial and may involve slow colonic transit, pelvic floor dysfunction, altered rectal sensation, and disturbances in intestinal motility. Chronic constipation can significantly impair psychological wellbeing and may lead to complications such as haemorrhoids, anal fissures, fecal impaction, and rectal prolapse.[5]

Management of constipation includes lifestyle modification, dietary fiber supplementation, adequate hydration, physical activity, and pharmacological therapy.[6] A wide variety of laxatives are available for treatment, including bulk-forming agents such as Ispaghula, stool softeners such as liquid paraffin, osmotic purgatives such as lactulose, stimulant purgatives such as bisacodyl and sodium picosulphate, and newer prokinetic agents such as prucalopride.[7] Although many of these agents are effective, the choice of therapy often varies depending on physician preference, patient acceptability, cost, convenience, and drug availability.

In this context, the concept of developing a personal formulary becomes highly relevant. The World Health Organization advocates rational drug use, which requires that patients receive medications appropriate to their clinical needs, in doses that meet individual requirements, for an adequate period, and at the lowest possible cost.[8] A personal formulary encourages clinicians to critically compare available therapeutic options based on objective criteria such as efficacy, safety, cost, and convenience rather than prescribing habits or promotional influence.[9]

Developing a personal formulary for constipation among residents of Pharmacology can strengthen evidence-based prescribing skills and promote rational use of laxatives in tertiary care settings.

MATERIALS & METHODS

This study was carried out in the Department of Pharmacology, IGIMS, Patna among the residents of Department of

Pharmacology. In case of any discrepancies, experts from the Dept. of Gastroenterology were consulted.

Personal formulary for therapy of constipation was developed by using drug database available under Janaushadhi. The Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) is a major initiative of the Department of Pharmaceuticals, Government of India, aimed at making high-quality generic medicines available to the public at affordable prices. Initially launched in 2008 and later strengthened in 2015, the programme functions through dedicated retail outlets called Janaushadhi Kendras, where medicines and surgical products are sold at prices considerably lower than branded alternatives. [10,11] Residents were taught about how to analyze and give score (α) to drugs used for constipation available under this scheme.

Four parameters according to P-drug concept of Joshi and Jayawick Ramarajah, efficacy (0.4), safety (0.3), cost (0.2) and convenience (0.1) were taken into consideration for each group and their drugs.[12]

1. Efficacy was derived according to the efficacy profile written in standard text books. Drugs with more efficacy were given higher score.
2. Safety of a drug were described according to the side effect profile written in standard text books. Drug with more side effects were given lower score.
3. Cost was compared by taking cost of drugs from Janaushadhi database.
4. Convenience was compared according to the availability of drug, dosage form, dosage schedule, route of administration.

Score was given to each four parameters from 1 to 10 for each drug. Each parameter was given a fractional numerical rating (β) according to the importance i.e. 0.4 for efficacy, 0.3 for safety, 0.2 for cost and 0.1 for convenience. Score (α) was multiplied by fractional numerical rating (β) to get total score ($\gamma=\alpha \times \beta$). Higher total score indicates a better value. The drug with the highest score became the personal drug choice. Then the senior residents and postgraduate kept a copy of personal drug description as a personal formulary.

RESULT

The following commonly used laxatives available under Janaushadhi and routinely prescribed in tertiary care settings were evaluated.

Table 1: Drugs used in the treatment of Constipation

Drug	Dosage Form	Dose	Frequency	Route	Cost of Treatment
Lactitol and Ispaghula	Powder	10g and 3.5g	Once daily	Oral	₹31.25/day
Lactulose	Syrup	10g/15ml	Once daily	Oral	₹8.55/day
Ispaghula (Psyllium husk)*	Powder	10g	Once daily	Oral	₹16.00/day
Magnesium hydroxide & Aluminium Hydroxide & Dimethicone	Tablet	250mg & 250mg & 50mg	Twice daily	Oral	₹1.12/day
Bisacodyl	Tablet	5mg	Once daily	Oral	₹0.56/day
Liquid paraffin & milk of magnesia &sod. picosulphate	Suspension	3.75mL & 11.25ml & 10mg	Once daily	Oral	₹4.71/day
Prucalopride	Tablet	1mg	Once daily	Oral	₹11.20/day

Table 2: Selection of Personal Formulary from Drug Groups available for Constipation

Drug Group	Efficacy (0.4)	Safety (0.3)	Cost (0.2)	Convenience (0.1)	Total
Bulk-forming agents	9 (3.6)	9 (2.7)	6 (1.2)	7 (0.7)	8.2
Osmotic purgatives	9 (3.6)	8 (2.4)	7 (1.4)	9 (0.9)	8.3
Stimulant purgatives	8 (3.2)	5 (1.5)	10 (2)	9 (0.9)	7.6
Stool softeners	7 (2.8)	6 (1.8)	8 (1.6)	6 (0.8)	7.0
Prokinetic agents	9 (3.6)	7 (2.1)	6 (1.2)	9 (0.9)	7.8

Table 3: Selection of Personal Drugs for Constipation

Drug	Efficacy (0.4)	Safety (0.3)	Cost (0.2)	Convenience (0.1)	Total Score
Lactulose	9 (3.6)	7 (2.1)	7 (1.4)	9 (0.9)	8.0
Ispaghula (Psyllium Husk)*	9 (3.6)	9 (2.7)	6 (1.2)	8 (0.8)	8.3
Lactitol and Ispaghula	9 (3.6)	7 (2.1)	4 (1.2)	7 (0.7)	7.6
Magnesium hydroxide & Aluminium Hydroxide & Dimethicone	8 (3.2)	6 (1.8)	10 (2.0)	7 (0.7)	7.7

*Ispaghula as a standalone formulation is not available under Janaushadhi but is available as Over-the-counter (OTC) drug.

Among the drugs available under Janaushadhi, Lactulose syrup obtained the highest total weighted score, it was selected as the personal formulary drug for constipation, but if we compare all of the drugs that are available in the market, Ispaghula as a standalone combination scored the highest and hence can also be used for the treatment of Constipation.

Table 4: Personal Formulary of Lactulose Syrup for Constipation

Dosage	Constipation: 15-30ml orally once or twice daily
WHAT TO TELL THE PATIENT	
Information	Lactulose is an osmotic laxative that softens stool by drawing water into the intestine and promotes bowel movement.
Side Effects	Flatulence, abdominal bloating, cramps, diarrhoea with excessive doses.
Contraindications	Intestinal obstruction, galactosemia; caution in diabetics and severe electrolyte imbalance.
Instructions	Take with water. Adequate fluid intake and high-fibre diet should be maintained.
Next Appointment	Review after 1–2 weeks if symptoms persist.
Follow-up	Long-term constipation requires evaluation for secondary causes.

DISCUSSION

Rational drug use requires that patients receive medications appropriate to their clinical needs, in doses that meet their individual requirements, for an adequate duration, and at the lowest possible cost.[13] The concept of personal formulary development encourages residents to critically evaluate therapeutic options using objective criteria rather than relying solely on routine prescribing habits or promotional influence.

In the present study, commonly used laxatives from different pharmacological groups were evaluated using the weighted criteria of efficacy, safety, cost, and convenience in accordance with the WHO Guide to Good Prescribing and the P-drug concept proposed by Joshi and Jayawick Ramarajah.

Lactulose syrup achieved a high overall score because it demonstrated excellent efficacy, good safety profile, and satisfactory convenience. Lactulose acts as an osmotic purgative by retaining water within the intestinal lumen, thereby softening stools and promoting bowel evacuation. It has been given an efficacy score of 9 as it is effective in both acute and chronic constipation, has a predictable therapeutic response and there's less risk of tolerance compared to other osmotic laxatives. The safety score of 7 reflects its moderate safety profile, as lactulose is minimally absorbed from the gastrointestinal tract and therefore produces very few systemic adverse effects. Common adverse effects such as bloating, flatulence, and mild abdominal discomfort are usually tolerable and decrease with continued use. A moderate cost score of 7 was assigned because lactulose is more expensive than conventional stimulant laxatives or saline purgatives, especially when prolonged therapy is required, although it still remains affordable and widely available in most

healthcare settings. The convenience score of 9 was given because lactulose is available in easy-to-administer oral syrup formulations, has good patient compliance, and can be safely used for long durations without significant risk of dependence or habit formation.[14]

Ispaghula (psyllium husk) received a high efficacy score of 9 because it is an effective bulk-forming laxative that increases stool bulk and promotes physiological bowel evacuation. It improves stool frequency, consistency, and ease of defecation, making it useful for chronic constipation and long-term management. The drug was given a high safety score (9) due to its minimal systemic absorption and low incidence of adverse effects. It is generally well tolerated and can be safely used in elderly individuals, pregnant women, and patients requiring prolonged therapy. However, adequate fluid intake is necessary to prevent bloating or intestinal obstruction. The comparatively lower cost score (6) was assigned because standalone ispaghula preparations are not available under the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) and are mainly available as branded or combination formulations, increasing treatment cost. Its convenience score was high (8) because it is administered orally, usually once or twice daily, and is suitable for long-term use, although some patients may find the granular texture less palatable.

The combination of lactitol and ispaghula obtained a slightly lower total score (7.6) despite having efficacy and safety scores comparable to lactulose as bulk-forming agents require adequate fluid intake to prevent intestinal obstruction and may produce bloating or abdominal fullness, especially during initiation of therapy as well as a slower onset of action resulting in a lower convenience score of 7. The other major limitation of this combination is its higher cost, as fiber supplements and combination preparations are relatively expensive for long-term therapy; therefore, it received a lower cost score of 4. Despite these disadvantages, the combination remains a safe and effective option for chronic constipation.

The preparation containing magnesium hydroxide, aluminium hydroxide, and dimethicone received the lowest total weighted score (7.7). Magnesium hydroxide acts as a saline osmotic laxative by drawing water into the intestinal lumen and stimulating bowel evacuation, while dimethicone reduces gaseous discomfort and bloating. Although the preparation is effective in relieving constipation and associated dyspeptic symptoms, its efficacy score was slightly lower (8) because saline laxatives generally produce less predictable long-term bowel regulation compared with lactulose-based regimens. Safety was significantly lower (6) due to the risk of systemic electrolyte disturbances, particularly hypermagnesemia in patients with renal impairment. However, this preparation received the highest cost score (10) because these agents are inexpensive, widely available, and economically suitable for short-term symptomatic treatment. Convenience was moderate (7) since the drug is easy to administer orally but may require repeated dosing and careful monitoring in susceptible patients. Overall, despite its affordability, the lower safety profile reduced its suitability as a preferred personal formulary drug for chronic constipation.

Bulk-forming agents received high safety and convenience scores because they mimic natural dietary fiber and are suitable for long-term use. They improve stool bulk and frequency with minimal systemic adverse effects. However, their efficacy depends on adequate hydration and patient compliance.[15]

Bisacodyl and sodium picosulphate are stimulant purgatives that increase colonic motility and fluid secretion. They have been scored slightly lower as although these drugs provide rapid symptomatic relief, they are less ideal for long term use. However, prolonged use may cause abdominal cramps, electrolyte imbalance, and

dependence, which reduced their safety scores.[16]

Liquid paraffin was assigned lower scores because prolonged use may interfere with absorption of fat-soluble vitamins and may rarely cause lipoid pneumonia due to aspiration, particularly in elderly patients. Although it is effective as a stool softener, its long-term use is generally discouraged.[17]

Prucalopride, a selective 5-HT4 receptor agonist, demonstrated high efficacy in chronic refractory constipation due to its prokinetic action. However, its high cost and limited availability significantly reduced its overall score despite good therapeutic efficacy.[18]

After weighted comparison of all parameters, Lactulose emerged as the preferred personal formulary drug for constipation because it provided the best balance of efficacy, safety, affordability, and convenience. But Ispaghula's high safety and efficacy profile has influenced its comparison with Lactulose.[19] The exercise demonstrated how systematic evaluation and objective scoring can guide rational prescribing and improve clinical decision-making among residents.

CONCLUSION

By applying the principles of rational drug use and the P-drug concept with greater emphasis on efficacy and safety followed by cost and convenience, Lactulose syrup emerged as the most suitable personal formulary drug for constipation among the evaluated laxatives but if we compare all drugs available as Over-the-counter medications for treatment of Constipation, Ispaghula can also be used. Although, Ispaghula has demonstrated excellent safety and suitability for long-term use, Lactulose has lower cost with acceptable safety and convenience. This structured exercise enabled residents of Pharmacology to critically appraise available therapeutic options using objective criteria and evidence-based literature rather than routine prescribing habits. Development of a personal formulary through systematic evaluation promotes rational, safe, effective, and economical prescribing practices in tertiary care settings.

Declaration by Authors

Ethical Approval: No patients or vulnerable groups were included in the study. Only the residents of Department of Pharmacology were included and hence there was no need for ethical clearance.

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Conflict of Interest: The authors declare no conflict of interest.

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