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Effectiveness of Gum Chewing on PEG Related Intake Adherence, GI Side Effects, and Bowel Preparation in Colonoscopy Patients: Randomized Controlled Trial

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Abstract: ***Objective: To evaluate the effectiveness of Gum Chewing on Polyethylene Glycol (PEG) Related Intake Adherence, GI Side Effects and Bowel Preparation among Patients Undergoing Colonoscopy. Methods: Quantitative research approach with true experimental design with single blinded block randomization was employed. This study was conducted in ILBS Hospital, New Delhi, India from November - December 2021. Patients were randomly allocated into two groups; an experimental group or a control group, n=30 in each group. In the control group, patients drank a PEG solution according to the general protocol. For the experimental group, patients had to chew one stick of sugarless gum during the pause interval of drinking the PEG solution. All the tools were having adequate validity and reliability. With normally distributed data, parametric tests were employed. Results: In experimental group there was a significant difference in Intake Adherence related to PEG solution, GI side effects including Abdominal discomfort (t=15.15, p<0.001), abdominal bloating (t=10.43, p<0.001) and INVR score (t=9.00, p<0.001) between the groups. In terms of Bowel Preparation there was an improvement seen in the experimental group as compared to the control group however, no significant difference (t=5.21, p=0.05). Moderate negative correlation (r= - 0.33, p< 0.05) was found between total amount of fluid taken and INVR score. Discussion: In the present study, total time spent in intake of PEG solution (min) in experimental group was found to be highly significant at p<0.001 level. Similar Findings were shown by Jisun lee, 2016, the gum - chewing participants showed an ability to ingest the PEG solution approximately 23 minutes faster than the control group patients. In the present study, abdominal discomfort and INVR score decreased in the experimental group. Similar findings were also found in research conducted by Jisun lee et al., 2016 and Sayilan. A., et al 2020. Conclusion: Gum chewing with PEG solution does not reduce bowel cleanliness, but it does help alleviate the abdominal discomfort, nausea, vomiting, and retching that come with this process, resulting in higher intake adherence. Future research needs to focus on standardizing the usage of gum chewing in therapeutic settings.***

Keywords: PEG, Gum Chewing, Intake Adherence, INVR, Bowel Preparation and Colonoscopy

1. Introduction

Colorectal cancer (CRC) is a major global health concern, ranking third among diagnosed cancers in males and second in females worldwide (Veettil et al., 2021). Annually, Europe sees over 432, 000 new CRC cases and 212, 000 deaths, with age - standardized rates of 29.6 and 12.4 per 100, 000, respectively. Globally, CRC results in more than a million new cases each year, with a mortality rate exceeding 40%. In the United States alone, CRC accounts for 50, 000 deaths annually, with treatment costs surpassing $250, 000 per patient. Representing 10% of global cancer deaths, CRC is notably increasing in emerging nations like India (Kuipers et al., 2015).

Despite the rising incidence of CRC in India, accurate statistics are challenging due to ineffective screening and asymptomatic cases (WHO, 2020). Colonoscopy is crucial for early CRC detection but is often perceived as invasive, uncomfortable, and costly (Triantafillidis, Vagianos, & Malgarinos, 2015). Technological advancements have improved colonoscopy, yet suboptimal bowel preparation remains a significant issue, leading to increased costs and the need for repeat procedures (Huynh et al., 2015). Pre - procedural bowel preparation is frequently cited as the most challenging aspect by patients, with taste - related issues impacting adherence (Kamran et al., 2020).

Polyethylene glycol (PEG), a common bowel preparation solution, faces challenges due to its high volume, prompting exploration of alternatives like sodium picosulfate (Na PICOSUL) (Jaiswal & Chaudhary, 2019). Innovations aimed at improving PEG's palatability, such as adding flavorings or using sulfate - free formulations, have shown promise (Choi et al., 2013; Di Palma et al., 2009). Chewing gum has emerged as a cost - effective method to expedite bowel movements post - colonoscopy, supported by evidence of its gastrointestinal benefits (Chan & Law, 2007). This study explores gum chewing's potential to enhance patient adherence, minimize side effects, and optimize bowel preparation in colonoscopy recipients.

2. Background

In resource - limited healthcare settings, cost - effective interventions are crucial. Colonoscopy often suffers from poor bowel preparation, PEG solution intolerability, and associated patient costs. Chewing gum presents a simple, affordable intervention that can alleviate discomfort,

improve bowel preparation, and reduce GI side effects during colonoscopy.

Inadequate bowel cleanliness affects one - third of colonoscopy candidates, increasing complications and costs. While PEG solution is effective, its unpleasant taste leads to patient reluctance. Sham feeding, like gum chewing, stimulates the cephalic - vagal response without adverse effects, offering a safe, cost - effective solution.

Studies have shown that gum chewing positively impacts gastrointestinal motility, postoperative recovery, and patient satisfaction, suggesting its potential as an adjunct to bowel preparation for colonoscopy. This study aims to evaluate gum chewing as a straightforward and safe intervention to enhance gastrointestinal movement, reduce transit time, and improve overall patient adherence to colonoscopy preparation.

3. Methodology

This true experimental posttest control - only study was conducted at the Institute of Liver and Biliary Sciences, New Delhi, from November to December 2021. The study involved 60 patients aged 18 and above undergoing colonoscopy. Using a block randomization technique, participants were divided into experimental (n=30) and control (n=30) groups.
Study Design: Randomized Controlled Trial

Location: Institute of Liver and Biliary Sciences, New Delhi

Duration: November to December 2021

Sample Size: 60 patients

Sample Size Calculation: To account for a 20% dropout rate, 60 patients were randomly allocated (30 per group) using permuted block randomization.

Subjects & Selection Method: Patients scheduled for elective colonoscopy at ILBS were randomly assigned to experimental and control groups.

Experimental Group: Received a protocol combining PEG solution with gum chewing. Patients took 2L of PEG solution at 250 ml (about 8.45 oz) every 15 minutes, chewing sugarless gum for 10 minutes after each glass, and additional clear liquids with gum every 2 hours until the colonoscopy.

Control Group: Followed routine care for colonoscopy preparation.

Procedure: Patients in the experimental group were instructed to take 2L of PEG solution along with sugarless sweet mint - flavored chewing gum. They were to consume 250 ml of PEG solution every 15 minutes or faster, chew one stick of gum for at least 10 minutes after each glass and discard the gum before the next glass. After finishing the 2L PEG solution, patients could drink clear liquids as tolerated and chew one stick of gum every 2 hours for at least 10 minutes until the colonoscopy. They recorded the time, amount of PEG solution, clear liquids consumed, and the number of discarded gums.

Inclusion Criteria: Adults ≥18 years, scheduled for elective colonoscopy, able to chew gum.

Exclusion Criteria: Critically ill patients, those on antiemetic therapy, or with psychiatric issues preventing adherence.

Formal approval was obtained, and informed consent was secured. The experimental group followed an evidence - based gum chewing protocol, while the control group adhered to standard preparation methods. Data collection included interviews and assessments by the colonoscopist.

Statistical analysis
The Data collected from 60 patients were entered into a spreadsheet of Microsoft office excel for windows 2010. The collected data was sorted, double checked, coded, and decoded for statistical analysis. The obtained data was analyzed employing descriptive and inferential statistics using SPSS version 22.2. Normality of data was assessed using the Kolmogorov Smirov test. For all variables data was found to be normally distributed. Hence, parametric tests are applied to analyze the data.

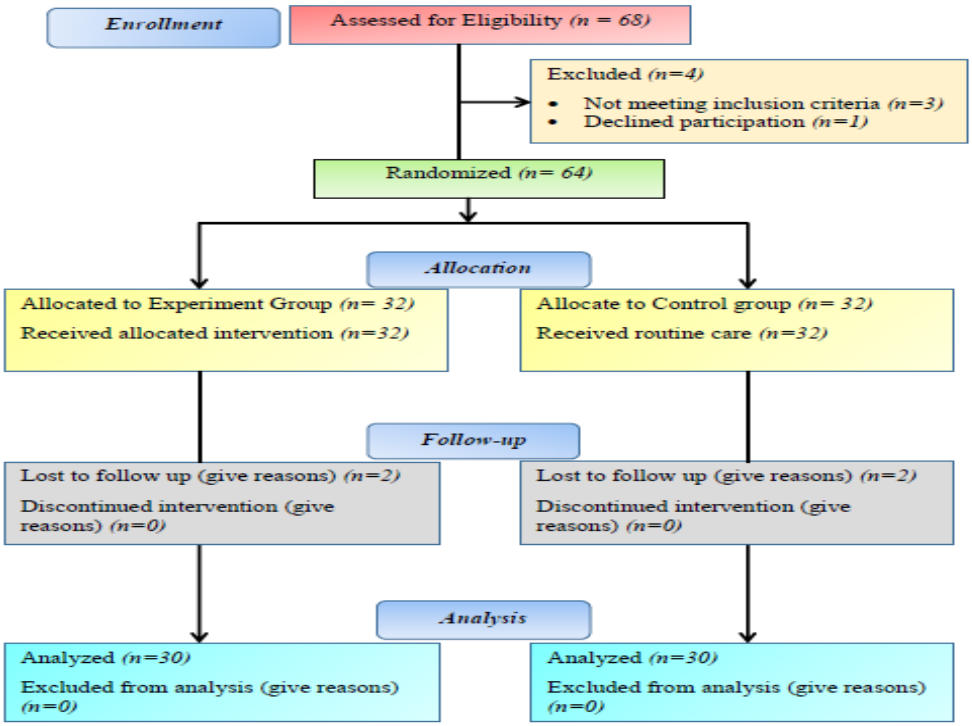

Figure 1: CONSORT Flow Diagram

Data collection tools and procedure

The tools used for data collection used by investigators were both standardized and self - developed after that verified by experts. The reliability and pilot study of data collection tools was checked.

Interview form

It consists of questions related to socio - demographic variables, four items including Age, Gender, Marital Status and Educational Status and clinical profile questions made of five items including diagnosis, indications for colonoscopy, history of previous colonoscopy, findings of colonoscopy and BMI. Additionally, four items which include time spent in ingesting the whole PEG solution in minutes, total amount of PEG solution taken, extra fluid taken other than PEG solution, total amount of fluid taken in milliliters.

Evaluation of GI side effects and bowel preparation

GI side effects include abdominal discomfort, nausea, vomiting, and retching. The Numerical Rating Scale (NRS), ranging from 0 (no discomfort) to 10 (worst discomfort), was used to measure symptoms during colonoscopy day interviews. Higher numbers indicate more severe symptoms. This tool is freely accessible and can be graphically or verbally delivered. The Rhodes Index for Nausea, Vomiting, and Retching (INVR) uses an 8 - item, 5 - point Likert scale to measure symptoms over the past 12 hours. Scores range from 0 to 32, with higher scores indicating greater distress. Some items are reverse scored. Boston Bowel Preparation Scale was chosen as an appropriate scale to assess bowel preparation. The Boston Bowel Preparation Scale (BBPS) was used by the colonoscopist to assess bowel preparation in patients undergoing colonoscopy in the procedure room.

4. Result

Characteristics of the patients

There were no differences in the typical characteristics or histories between the two study groups, suggesting that the randomization was effective. The total number of subjects was 60, including 41 men and 19 female and in which maximum patient don does not have any previous experience of colonoscopy (Table 1).

Table 1: Frequency and Percentage Distribution of Socio Demographic and clinical variables among patients undergoing Colonoscopy in the Experimental and Control group.

Socio - Demographic & clinical variables	Experimental Group f (%) n_1=30	Control Group f (%) n_2=30	t /χ2	df	p value
Age (in years) (Mean±SD)	47.37±13.61	51.43±13.64	1.15	58	0.25
Gender					
Male	20 (66.7%)	21 (70.0%)	0.07	1	0.50
Female	10 (33.3%)	9 (30.0%)			
Diagnosis					
CLD	4 (13.3%)	4 (13.3%)	1.4	4	0.43
Colon Cancer	3 (10.0%)	1 (3.3%)			
NASH	4 (13.3%)	5 (16.7%)			
Others	1 (3.3%)	2 (6.7%)			
Not yet diagnosed	18 (60%)	18 (60.0%)			

Indications of colonoscopy					
Bleeding	9 (30.0%)	8 (26.7%)	2.3	4	0.45
Irregular bowel habits	10 (33.3%)	11 (36.7%)			
Abdominal pain	2 (6.7%)	3 (10.0%)			
Loss of appetite & weight loss	7 (23.3%)	8 (26.7%)			
Others	2 (6.7%)	0			
History of previous colonoscopy					
Yes	9 (30.0%)	14 (46.7%)	1.7	1	0.14
No	21 (70.0%)	16 (53.3%)			
Findings of colonoscopy					
Bleeding Varices	5 (16.7%)	5 (16.7%)	2.7	5	0.32
Ulcers	9 (30.0%)	7 (23.3%)			
Ulcerative Colitis	2 (6.7%)	4 (13.3%)			
Polyps	5 (16.7%)	2 (6.7%)			
Others	2 (6.7%)	2 (6.7%)			
No significant findings	7 (23.3%)	10 (33.3%)			
BMI (kg/m^2) (Mean±SD)	23.00±3.9	23.10±4.1	0.09	58	0.92

$p \geq 0.05$; Not Significant

Comparison between experimental and control group in terms of intake adherence

The gum chewing with PEG was found to be significant with $p < 0.05$, in terms of intake adherence (Table 2).

Table 2: Mean, Standard Deviation, Mean Difference, t and p value of intake adherence related to PEG solution among patients undergoing colonoscopy in experimental and control groups

Intake Adherence	Experimental Group (n_1=30) (Mean ± S. D)	Control Group (n_2=30) (Mean ± S. D)	MD	t - test	p value
Total time spent in intake of PEG solution (min)	91.50±17.77	119.00±9.59	27.50	7.4	<0.001**
Total amount of PEG solution taken (ml)	2000.0±0.00	1933.33±112.44	66.66	3.2	0.003**
Extra amount of fluid taken (ml)	476.67±225.04	201.79±240.42	278.33	5.7	<0.001**
Total amount of fluid taken (ml)	2476.67±225.04	2131.67±215.95	345.00	6.0	<0.001**

** $p<0.001$; Highly Significant, df = 58

Comparison between experimental and control group in terms of GI side effects and bowel preparation

The gum chewing was found to be effective in reducing GI side effects i. e., nausea, vomiting, retching, abdominal discomfort, and bloating. However, there is no significant difference in bowel preparation (Table 3).

Table 3: Mean, Standard Deviation, Mean Difference, t and p value of GI side effects and bowel preparation among patients undergoing colonoscopy in experimental and control groups

GI Side effects and bowel preparation	Experimental Group (n_1=30) (Mean ± S. D)	Control Group (n_2=30) (Mean ± S. D)	MD	t - test	p value
Abdominal discomfort score	1.50±1.13	6.23±1.27	4.73	15.15	**<0.001****
Abdominal bloating score	1.37±1.29	5.47±1.71	4.10	10.43	**<0.001****
INVR score	3.00±2.61	12.93±5.45	9.93	9.00	**<0.001****
BBPS score	7.00±1.28	5.13±1.47	1.86	5.21	0.05

** $p<0.001$; Highly Significant, $p \geq 0.05$; Not Significant, df= 58

Correlation between total amount of fluid taken with abdominal discomfort, abdominal bloating, INVR and bowel preparation in patients undergoing colonoscopy in experimental group

Pearson's Correlation was used to find the relationship between total amount of fluid taken and abdominal discomfort, abdominal bloating, BBPS score and INVR score. The computed 'r' value was moderate negative for INVR score and significant, as evident from the respective p value below 0.05 level of significance. So, it was concluded that the INVR score was reduced as the total amount of fluid intake increased among patients undergoing colonoscopy in the experimental group (Table 4, figure 2).

Table 4: Mean, Standard Deviation, r value and p value of Total amount of fluid taken (ml), abdominal discomfort score, INVR score and bowel preparation score in experimental group.

Experimental group		Total amount of fluid taken	Abdominal discomfort score	Abdominal bloating score	INVR score	BBPS score
Total amount of fluid taken (ml)	Mean	2476.67	1.50	1.37	3.00	7.00
	SD	225.04	1.13	1.29	2.61	1.28
	r	1	- 0.12	- 0.41	- 0.33	0.17
	p value	-	0.52	0.94	0.03*	0.36

$p< 0.05$; *Significant $p \geq 0.05$; Not Significant

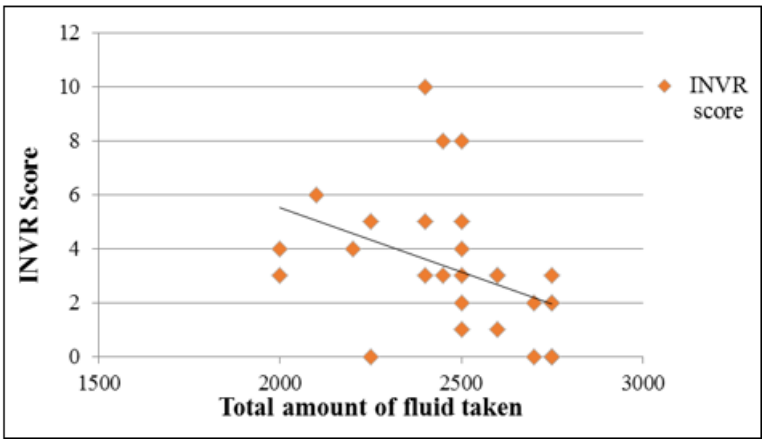

Figure 2: Scatter plot showing Correlation between the total amount of fluid taken and INVR score

5. Discussion

The present study included 60 patients, equally divided into an experimental group and a control group. The mean age of patients in the experimental group was 47.37 years (±13.61), while in the control group, it was 51.43 years (±13.64). These findings align with previous studies, such as Fang et al. (2017), where the mean ages were 46.8 (±12.2) and 48.7 (±11.3) in similar groups. Another study by Ou et al. (2014) also showed comparable results with mean ages of 56.9 (±16.5) and 58.3 (±15.9) in their respective groups.

In our study, 60% of patients undergoing colonoscopy in both groups were not yet diagnosed with any specific condition, and 13.3% were diagnosed with chronic liver disease (CLD). These results are consistent with Fang et al. (2017), where most patients had no significant disease. Additionally, 32.1% of patients in the experimental group underwent colonoscopy due to bleeding and irregular bowel habits, compared to 36.7% in the control group with irregular bowel habits. This mirrors findings by Ergul et al. (2014), which indicated anemia due to bleeding as a common reason for colonoscopy.

Regarding the outcomes of colonoscopy, 30% of patients in the experimental group were found to have ulcers, while 23.3% had no significant findings. In the control group, 33.3% had no significant findings, and 23.3% had ulcers. These results are in line with Ergul et al. (2014), where many patients had no significant findings.

Intake adherence, particularly the time spent consuming the PEG solution for bowel preparation, showed a mean of 90.54 minutes (±17.55) in the experimental group and 118.93 minutes (±9.94) in the control group, with a highly significant p - value (<0.001). Jisun Lee (2016) also found that gum - chewing participants ingested the solution faster by 23 minutes, indicating a statistically significant difference ($p = 0.018$).

Gastrointestinal (GI) side effects, including abdominal discomfort, were significantly lower in the experimental group, with a mean score of 1.54 (±1.17) compared to 6.21 (±1.25) in the control group ($p < 0.001$). This is supported by Jisun Lee et al. (2016), who reported a 26% reduction in abdominal discomfort in the experimental group ($p = 0.015$). Sayilan et al. (2020) also found significantly lower pain severity in the experimental group ($p < 0.05$).

Abdominal bloating was also significantly lower in the experimental group (mean score 1.46 ± 1.29) compared to the control group (5.36 ± 1.70), with a p - value <0.001. Jisun Lee et al. (2016) found related results, with a 25% reduction in bloating ($p = 0.025$). Additionally, the INVR score was significantly lower in the experimental group (3.21 ± 2.57) versus the control group (5.36 ± 1.70), with a highly significant p - value (<0.001). Sayilan et al. (2020) reported lower severity of nausea and vomiting in the experimental group, consistent with our findings.

Bowel preparation quality, measured by the BBPS score, was not significantly different between the groups in our study, similar findings by Fang et al. (2017) and Jisun Lee et al. (2016). Pearson's Correlation analysis showed no significant relationship between the total fluid intake and abdominal discomfort or bloating, but a moderate negative correlation with the INVR score.

In conclusion, this study highlights the importance of factors like gum - chewing in improving PEG solution intake adherence and reducing GI side effects, though more research is needed to explore these correlations further.

6. Conclusion

The chewing gum protocol is feasible and transferable. It is harmless with low cost. It is a noninvasive, which is favorable with the PEG solution for the patient's undergoing colonoscopy. There is not much extra skill and workload for staff. There is not much expenditure for the medical system as well. However, it brings much more comfort and helps in reducing the GI side effects in patients.

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