Original Article

# Application of a New Protocol for a Study of Colonic Transit Using Radiopaque Markers in Functional Constipation for a Population with Rapid Gut Transit

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## Abstract

**Background:** Indians do not fit the definition of slow transit constipation (STC) according to Western standards because of their quick gut transit. The colonic transit study (CTS) can discriminate between patients with severe specific motility problems, such as Hirschsprung's disease and chronic intestinal pseudo-obstruction, and healthy participants with optimal sensitivity and specificity when using a new technique in the Indian population. The study's goal was to establish the appropriate cutoff to distinguish between healthy participants and moderate abnormalities such as functional constipation. The study aimed to find out a cutoff value for STC compared to healthy volunteers in the Indian population using the new Indian protocol of CTS. **Materials and Methods:** This observational study was performed in the department of gastroenterology from August 2014 to February 2015. Twenty-one patients who fulfilled the criteria for Rome III functional constipation and eight healthy sex-matched volunteers were included in the study. Subjects were instructed to take 4, 3, and 3 capsules simultaneously (6 markers in each capsule) at 0, 12, and 24 h, respectively. An abdominal X-ray was taken at 36 h and 60 h. The patient group also underwent a thorough history, a clinical examination, and a balloon expulsion test as a screening test for fecal evacuation disorder. The data were compiled and analyzed. The best cutoff was determined by a receiver operating characteristic curve, and the sensitivity, specificity, and predictive values were determined. **Results:** There were a total of 21 patients with 14 males and 7 females. The majority (38.1%) had a frequency of 7/week. The predominant symptoms were hard stool (66.7%), sensation of blockage (85.7%), and straining (90.5%). The best cutoff to differentiate between normal and slow transit, in comparison to healthy volunteers, was calculated. Area under curve was computed to be 0.69 ($P = 0.001$) for 60 h and 0.71 ($P = 0.001$) for 36 h. When ≥4 and ≥1 markers were taken, the sensitivity and specificity were 100% and 25%, respectively. When ≥20 and ≥4 markers were taken, the sensitivity and specificity were 52% and 100%, respectively. No significant difference between right, left, or rectosigmoid segmental colonic transit time was found at 36 or 60 h. **Conclusion:** The new protocol to assess colonic transit in the Indian population with functional constipation may be used as a screening modality to find out the delayed transit constipation. However, this protocol has less sensitivity, specificity, and positive and negative predictive values for functional constipation compared to severe diseases such as Hirschsprung's disease and colonic pseudoobstruction.

**Keywords:** Colonic transit time, constipation, radiopaque markers

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## Introduction

Up to 28% of people in the population experience constipation as a medical issue. Constipation is one of the top five gastrointestinal illnesses that doctors diagnose in outpatient visits. Constipation uses up a lot of health-care resources due to its high prevalence. Constipation is defined differently by doctors and other healthcare professionals. Constipation, as a syndrome, is generally characterized by bowel symptoms including hard or infrequent stools, difficulty in passing them, or a feeling of incomplete evacuation. These symptoms can arise alone or as a result of another underlying condition. Most affected people have minor symptoms and are prescribed laxatives. The role of a gastroenterologist is to

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correctly identify the patient, who might benefit from further evaluation and appropriate management.[1] In an attempt to standardize the definition of functional constipation, Rome criteria were developed and revised in 2006 (Rome III).[2] According to the transit and anorectal functions, constipation is grouped into three types. Normal transit type, slow transit type, and pelvic floor dysfunction.[1] In the West, colonic transit study (CTS) using radiopaque markers is regarded as a straightforward screening procedure to identify slow transit constipation (STC) and fecal evacuation disorders (FED).[3] Utilizing 20 radiopaque markers consumed at 0, 24, and 48 h each, followed by an abdominal X-ray at 72 h, allows for the determination of gut transit time.[4] Due to quick intestinal transit, no marker was discovered to be maintained inside the belly after 72 h, making this approach unsuitable for Indians.[5]

Regarding food habits, intestinal physiology, health-care infrastructure, and patient perception and self-management of constipation, there are significant potential disparities between Asia and the West.[6] The colonial transit periods of people in China and India seem to be shorter than those in the West.[7] In the Indian population, the gut transit time is quite quick. Even though the Western community considers a frequency of at least three stools per week to be normal,[8] 99% of Indian population pass at least one stool per day.[9]

The CTS can discriminate between individuals with severe specific motility problems, such as Hirschsprung's disease and chronic intestinal pseudo-obstruction, and healthy participants with a respectable level of sensitivity and specificity using a new procedure in the Indian population. The optimal cutoff determined by receiver operating characteristic (ROC) curves was 30 and 14 markers, respectively, at 36 and 60 h.[5]

The level used to distinguish a minor anomaly such as functional constipation from healthy volunteers has not been studied till today, hence this study.

## Materials and Methods

The study was aimed at finding a cutoff value for STC compared to healthy volunteers in the Indian population using the new Indian protocol for colonic transit studies. The Department of Gastroenterology carried out the observational study from August 2014 to February 2015. Twenty-one patients who fulfilled the criteria for Rome III functional constipation were in the patient group. Pregnancy and other secondary causes of constipation were excluded. Eight healthy, sex-matched volunteers (doctors and staff members) were included. The study protocol was accepted by the research committee and ethics board.

### Method of study

At 0, 12, and 24 h, the subjects were instructed to take 4, 3, and 3 capsules simultaneously (6 markers per capsule). X-rays of the abdomen were collected at 36 and 60 h. The total number of retained markers was recorded. To measure segmental transit, three vertical lines were drawn: one from the midpoint of the sacral promontory to the midpoint of the inner pelvic brim on the right side; a second from the midpoint of the sacral promontory to the left anterior superior iliac spine; and a third from the midpoint of the sacral promontory to the left anterior superior iliac spine [Figure 1]. The right, left, and rectosigmoid parts of the abdomen were separated by these lines. The patient group also underwent a thorough history, a clinical examination, and a balloon expulsion test as a screening test for FED. Each patient underwent the balloon expulsion test using a Foley's catheter filled with 60 mL of air. The patient was told to bear down to expel the balloon in a commode while in a squatting position. The time taken to expel the balloon was noted. The data were compiled and analyzed. The best cutoff was assessed by an ROC curve, and the sensitivity, specificity, and predictive values were determined.

### Statistical analysis

The median and range were used to express numerical data. Chi-square was used to assess categorical variables. $P < 0.05$ was considered statistically significant. The number of retained markers at which the cutoff value should be set to distinguish between healthy and diseased people was evaluated by ROC curve. Using the optimal cutoff, sensitivity, specificity, positive and negative predictive values, and diagnostic accuracy were calculated by ROC curve.

## Results

There were a total of 21 patients with 14 (66.7%) males and 7 (33.3%) females. The majority (38.1%) had a frequency of 7/week, whereas only 5 (23.8%) patients had a frequency of 3/week. The predominant symptoms were straining (90.5%), sensation of blockage (85.7%), and hard stool (66.7%). Blood in stool and pain during defecation were present in 14.3% and 19% of patients, respectively [Table 1]. A history of digital evacuation of stool was present in 47.6% of patients. The

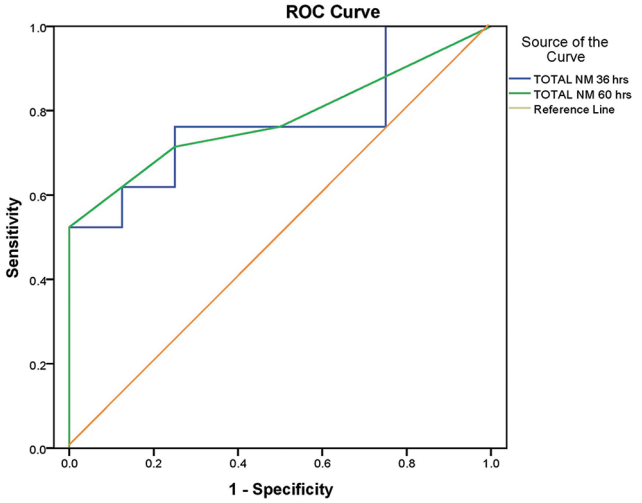


**Figure 1:** Area under receiver operating characteristic curves for abdominal X-ray at 36 and 60 h. ROC: Receiver operating characteristic, NM - Number of Markers

**Table 1: General characteristic of patient case**

| | Frequency (%) |
|---|---|
| Gender | |
| Male | 14 (66.7) |
| Female | 7 (33.3) |
| Frequency per week | |
| 2 | 2 (9.5) |
| 3 | 5 (23.8) |
| 4 | 3 (14.3) |
| 5 | 3 (14.3) |
| 7 | 8 (38.1) |
| Consistency | |
| Hard | 14 (66.7) |
| Semi solid | 5 (23.8) |
| Normal | 2 (9.5) |
| Blood in stool | |
| Yes | 3 (14.3) |
| No | 18 (85.7) |
| Painful defection | |
| Yes | 4 (19) |
| No | 16 (76.2) |

majority (71.4%) was taking laxatives regularly or as and when required. A history of sexual abuse was present in 19% of patients. Adequate physical activity was not present in 52.4% of patients, and adequate fiber intake was not present in 47.6% of cases. A nonvegetarian diet was implicated in the increase in symptoms in 52.4% of patients. Based on the Bristol stool scale, type 2 stool was present in the majority (42.9%) of patients, followed by Type 3 (14.3%). On a rectal examination, a high resting tone was present in 2 (9.5%) cases, and an abnormal perineal descent was present in three patients (14.3%). Balloon expulsion time was prolonged in 11 (52.4%) patients.

The best cutoff to differentiate between normal and slow transit, in comparison to healthy volunteers, was calculated. Area under curve (AUC) was computed as 0.71 ($P = 0.001$) for 36 h and 0.69 ($P = 0.001$) for 60 h. When ≥4 and ≥1 markers were taken, the sensitivity was 100% and specificity was 25%. When ≥20 and ≥4 markers were taken, the sensitivity was 52% and specificity was 100%. No significant difference between right, left, or rectosigmoid segmental colonic transit time was found at 36 or 60 h. There was no advantage to a single X-ray at 36 h or 60 h [Figure 1].

## Discussion

Western criteria for STC are different from those used in India. The markers were not retained in the abdomen at 72 h, in the Indian population due to rapid transit. In an attempt to find out the transit time for a group of people with slow colonial transit, various modifications of the Western protocol were made by different groups of authors.[5] At 0, 9, and 18 h, Nabar *et al*. administered 20 markers, and at 27 h, an abdominal X-ray was taken.[10] In a different study by Pai and Kurian, CTS was carried out according to a protocol that involved giving 20 radiopaque markers at 0, 12, and 24 h of each, followed by abdominal X-rays at 12, 24, and 36 h.[11] Recently, Ghosal UC developed a brand-new colonic transit research procedure that uses a single X-ray every 60 h to detect serious anomalies such as Hirschsprung's disease and persistent intestinal pseudo-obstruction in healthy people.

Our study group of patients was a functional constipation group according to ROME III criteria. When colonic transit in this group of patients was compared with that of healthy volunteers, it was found that the number of markers retained was higher in the latter group. Although the AUC was significantly different at 36 h and 60 h, the sensitivity, specificity, and predictive values were lower compared to the previous study. When four markers were taken at 60 h, specificity was 100%, compromising sensitivity to only 52%. Hence, this cutoff can be used to rule out the patient with normal transit, whereas those who have a marker >4 need further studies such as manometry or scintigraphy to confirm the delayed transit. The majority of the diagnostic criteria for irritable bowel syndrome distinguish it from organic disorders such as colon cancer.[12]

We could not differentiate any segmental distribution of markers either at 36 or 60 h in these patients. Moreover, there was no definite advantage of X-rays at 60 h over 36 h, or vice versa.

The small patient population was a drawback to our study and the controls' ages were not quite matched.

## Conclusion

The new protocol to assess colonic transit in the Indian population with functional constipation may be used as a screening modality to find out the delayed transit constipation. However, this protocol has less sensitivity, specificity, and positive and negative predictive values for functional constipation compared to severe diseases such as Hirschsprung's disease and colonic pseudoobstruction. Further studies with larger samples are needed to find the trade-off between high sensitivity and specificity using the present protocol or a lower time interval protocol.

### Ethical statement

The study was approved by the institutional Ethics Committee of Government Medical College, Kozhikode with Letter Number GMCKKD\RP 2014/IEC\04\07.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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