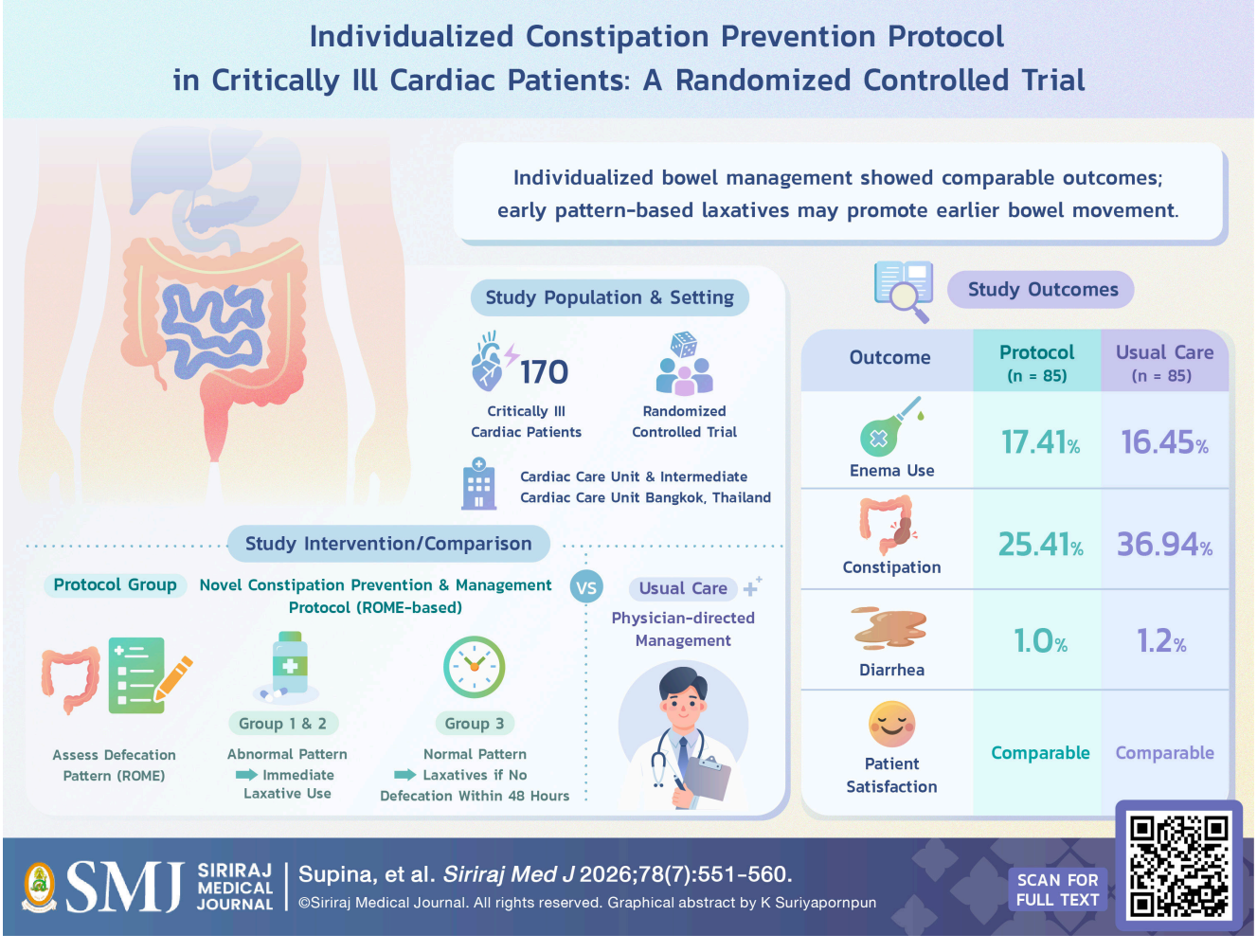
A Novel Constipation Prevention and Management Protocol Versus Physician-Directed Management of Constipation in Critically Ill Cardiac Patients: A Randomized Controlled Study

Pattanaporn Supina, M.Sc.[1], Churi Duanthet, B.N.S.[1], Siwaporn Khanha, B.N.S.[1], Phannita Wattanaruengchai, B.S.[2], Thananya Boonyasirinant, M.D.[3,*]

[1]Department of Nursing, Division of Cardiology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand, [2]Department of Pharmacy, Division of Pharmacy, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand, [3]Department of Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand.



**Corresponding author: Thananya Boonyasirinant*
E-mail: drthananyaa@yahoo.com
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ORCID ID: http://orcid.org/0000-0002-9149-3407
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ABSTRACT

Objective: To compare the efficacy of a novel constipation prevention and management protocol with that of routine physician-directed management of constipation in critically ill cardiac patients.

Materials and Methods: This randomized controlled trial was conducted in the cardiac care unit and intermediate cardiac care unit of a tertiary hospital in Bangkok, Thailand. A total of 170 patients were randomized and analyzed according to the intention-to-treat principle. Missing outcome data were handled using multiple imputation. The protocol group was further subdivided using the ROME criteria into Group 1 and Group 2 (abnormal patterns; received immediate laxatives) and Group 3 (normal pattern; received laxatives only if no defecation occurred within 48 hours). The primary outcome was enema use. Secondary outcomes included the incidence of constipation and diarrhea, and patient satisfaction. Data were analyzed using appropriate statistical methods.

Results: The incidence of enema use was 17.41% in the protocol group and 16.45% in the usual care group. Constipation occurred in 25.41% and 36.94% of patients, respectively, while diarrhea occurred in 1.0% and 1.2%. Patient satisfaction was comparable between groups ($p = 0.221$).

Conclusion: The individualized bowel management protocol did not significantly reduce enema use, constipation, or diarrhea compared with usual care. Exploratory findings suggest that early laxative administration based on defecation patterns may facilitate earlier bowel movement.

Keywords: Clinical protocols; defecation behavior; heart diseases; intensive care unit; laxative (Siriraj Med J 2026;78(7):551-560)

INTRODUCTION

Constipation is a common issue among patients in the cardiac care unit and is influenced by factors such as hemodynamic instability, electrolyte imbalances, fluid restriction, immobility, medication side effects, and loss of privacy. Because the healthcare team often prioritizes acute crisis management, constipation is often overlooked. The reported prevalence of constipation ranges from 51% to 83% in other countries[1-4] and is approximately 73% in Thailand.[5] Constipation can prolong the duration of mechanical ventilation, complicate ventilator weaning, and extend hospital length of stay.[3,4,6,7] Straining during defecation can increase blood pressure and lead to cardiovascular events, including congestive heart failure and arrhythmias.[8]

Both nonpharmacological and pharmacological methods are available for the prevention and management of constipation. Nonpharmacological approaches include promoting healthy bowel habits, encouraging physical activity, and ensuring adequate fiber and water intake.[9] However, these measures are often limited in critically ill patients, making laxatives a common management strategy. In critically ill patients, the initial treatment of constipation typically involves stimulant laxatives (e.g., bisacodyl or senna) or osmotic laxatives (e.g., lactulose or polyethylene glycol). Osmotic laxatives, however, may induce gas formation, resulting in abdominal distension, discomfort, and fluid shifts.[10] If patients do not respond to laxatives, more invasive methods, such as manual evacuation or the use of an enema, may be required. In critically ill patients with heart disease, particularly older adults or those with comorbidities, certain medications may complicate constipation management. These medications, such as angiotensin-converting enzyme inhibitors, antiplatelets, and anticoagulants, may increase the risk of adverse effects and complications related to laxatives or enemas.[11]

Several institutions, including the Royal Free Hospital in London and the Cardiff Critical Care Department at the University Hospital of Wales, have developed protocols for constipation management in intensive care units. Warren and Kent designed a bowel management protocol in a cardiac intensive care unit in which all patients received laxatives upon admission; however, the protocol group demonstrated a higher incidence of constipation within the first 96 hours compared with the control group.[12] Similarly, *Knowles et al.* reported no significant differences in the incidence of constipation or diarrhea before and after protocol implementation.[13] However, the findings remain inconclusive. *Guardiola et al.* reported that administration of polyethylene glycol on the first day after initiation of mechanical ventilation resulted in a significantly lower rate of defecation failure compared with initiation on day 4 (8.6% vs. 25%, $p < 0.01$).[14]

In Thailand, constipation management in critically ill patients remains inconsistent and largely depends on individual physicians' judgment. Given the limitations of

existing protocols, particularly their lack of consideration for individual defecation patterns, this study developed a novel constipation prevention and management protocol and compared its efficacy with that of routine physician-directed constipation management in critically ill cardiac patients.

MATERIALS AND METHODS

Study design and participants

This prospective randomized controlled trial investigated the effects of a constipation prevention and management protocol in critically ill cardiac patients. The study was conducted in the cardiac care unit and intermediate cardiac care unit of a tertiary hospital in Bangkok, Thailand. Patients were randomly assigned in a 1:1 ratio to either the protocol group or the usual care group. Ethical approval was obtained from the Institutional Review Board (Approval No. Si 539/2021). Written informed consent was obtained from all participants prior to enrollment. For patients who were unable to provide consent due to impaired consciousness or clinical instability, consent was obtained from their legally authorized representatives. The trial was retrospectively registered with the Thai Clinical Trials Registry (TCTR) under the identification number TCTR20241114002.

This study included patients admitted to the cardiac care unit and intermediate cardiac care unit between October 2021 and June 2023.

The inclusion criteria were:

1. Diagnosis of cardiovascular disease
2. Age ≥18 years
3. Glasgow Coma Scale (GCS) score > 8

The exclusion criteria were:

1. Diarrhea within 1 day prior to randomization
2. Nil by mouth for more than 24 hours
3. Daily laxative use within the previous week
4. Contraindications to laxatives, including allergies, coagulopathy, or rectal perforation
5. History of chronic constipation, irritable bowel syndrome, inflammatory bowel disease, intestinal ileus or obstruction, gastrointestinal bleeding, cirrhosis, or prior bowel surgery
6. Pregnancy at admission
7. Presence of a colostomy, ileostomy, or jejunostomy

Patients were screened and enrolled by co-authors (PS, CD and SK). The primary cardiac diagnoses leading to CCU admission (e.g., acute myocardial infarction, heart failure and other acute cardiovascular conditions) were recorded from the medical records as baseline clinical characteristics. The sample size was calculated based on the primary outcome of enema use during hospitalization. Using the n4Studies program, the calculation assumed a reduction in the proportion of patients requiring an enema from 20% to 5%. With a two-sided alpha of 0.05 and a power of 80% ($\beta = 0.20$), the required sample size was 76 patients per group. To account for a potential 10% dropout rate, the final sample size was increased to 85 patients per group, resulting in a total of 170 participants. Eligible patients were randomized into a control group (usual care) and an intervention group (protocol group) (Fig 1). Randomization codes were generated by PW using a computer-generated randomization scheme with a 1:1 allocation ratio. Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes prepared by PW, who was not involved in patient recruitment or outcome assessment. The envelopes were opened only after participants had been enrolled in the study. Due to the nature of the intervention, blinding of clinical staff and participants was not feasible; however, outcome data were collected from nursing records by investigators (PS, CD, and SK) according to predefined criteria. Bowel movement status was assessed and summarized daily at 8:00 a.m.

Study protocol

The control group received usual care, defined as physician-directed management of constipation (Fig 2). This included the administration of laxatives on the first day of admission or only after constipation developed. No formal assessment using the ROME criteria was performed in this group. The intervention group was assessed for bowel habits using the ROME criteria, and patients were categorized into three subgroups based on their defecation patterns:

- **Group 1**: Patients exhibiting at least one of the following characteristics:
  - Straining during defecation
  - Hard or lumpy stools
  - Sensation of incomplete evacuation
- **Group 2**: Patients exhibiting at least one of the following characteristics:
  - Sensation of anorectal obstruction during defecation
  - Need for manual maneuvers to facilitate defecation
  - Patients meeting criteria for both Group 1 and Group 2
- **Group 3**: Patients who did not exhibit any characteristics described in Groups 1 or 2.

Patients were classified into the usual care group and three intervention groups based on the aforementioned characteristics, after which tailored interventions were

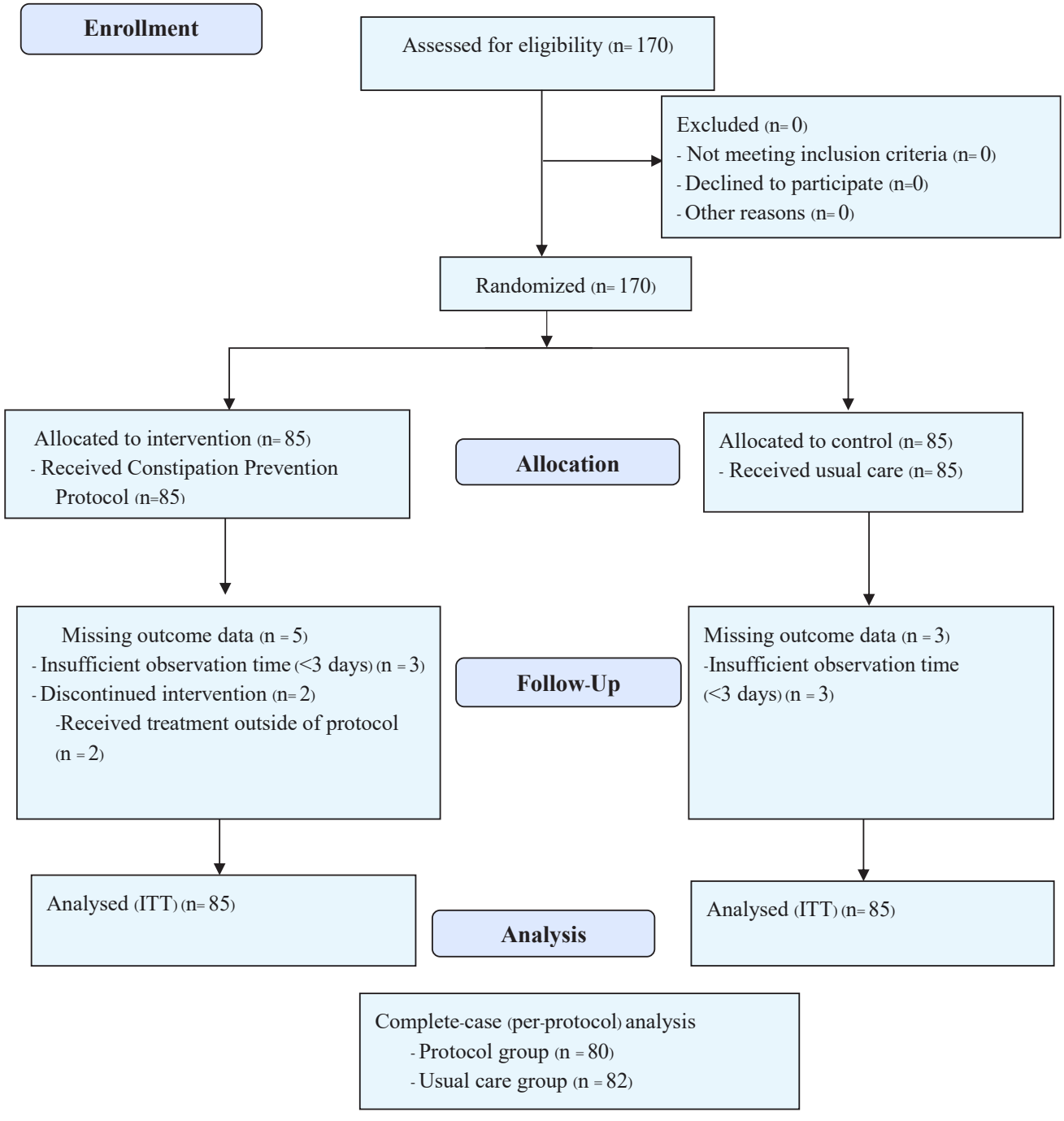


Fig 1. CONSORT flow diagram of participant recruitment, allocation, follow-up, and analysis.

implemented accordingly (Fig 2). In the intervention groups, constipation prevention and management were conducted according to a predefined stepwise protocol, with laxatives administered orally after breakfast at 8:00 AM.

Group 1 received lactulose syrup 20 mL on day 1. If no bowel movement occurred, the dose was increased to 40 mL on day 2. If defecation still did not occur, lactulose 40 mL combined with sennosides (7.5 mg) 2 tablets was administered on day 3. If no bowel movement occurred within 72 hours (day 4), evacuation and sodium phosphate enema were performed.

Group 2 received sennosides (7.5 mg) 2 tablets on day 1. If no bowel movement occurred, the dose was increased to 4 tablets on day 2. If defecation still did not occur, sennosides 4 tablets combined with lactulose 20 mL was administered on day 3. If no bowel movement occurred within 72 hours (day 4), evacuation and sodium phosphate enema were performed.

Group 3 did not receive prophylactic laxatives during

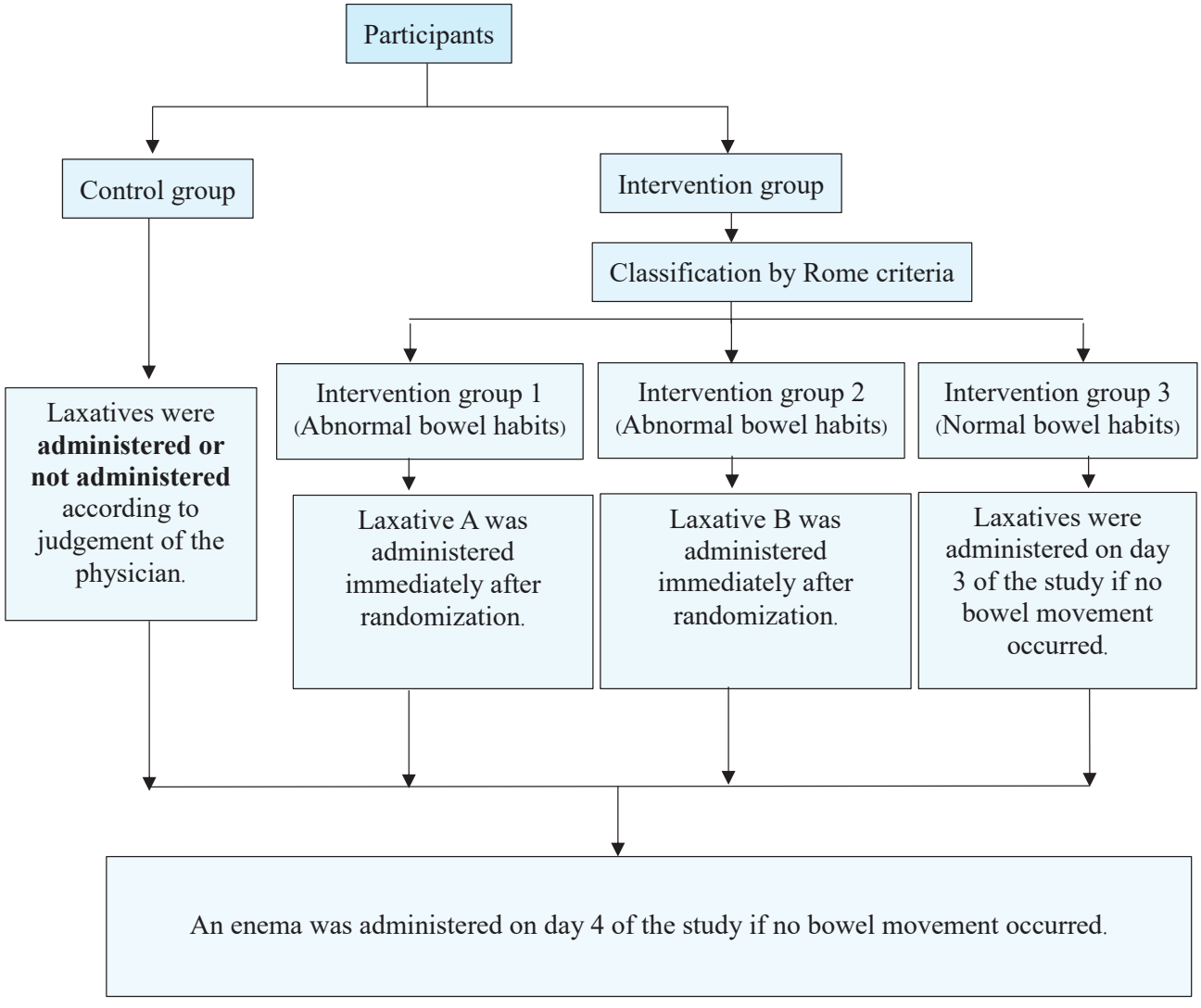


Fig 2. Flowchart of group assignment.

the first two days, and bowel movements were monitored. If no bowel movement occurred by day 3, sennosides (7.5 mg) 2 tablets were administered. If defecation still did not occur within 72 hours (day 4), evacuation and sodium phosphate enema were performed.

Study Outcomes were defined as follows:

Primary outcome

Enema administration rate: Defined as the proportion of patients who received an enema due to the absence of a bowel movement for ≥72 hours.

Secondary outcome

1. Constipation rate: Defined as the proportion of patients who had no bowel movement (stool passage) for ≥72 hours.

2. Diarrhea rate: Defined as the occurrence of three or more bowel movements per day, with stool characteristics classified as Type 6 or 7 according to the Bristol Stool Scale and a total stool volume exceeding 250 mL per day.[15]

3. Patient satisfaction: Satisfaction with bowel movements was assessed using a Likert-scale rating system, including bowel care and the use of laxatives. The questionnaire was administered using the same procedure for both groups. Participants were informed that their responses would remain confidential and would not affect their medical care.

Statistical analyses

All randomized participants were included in the analysis according to the intention-to-treat principle. Missing outcome data were handled using multiple imputation based on clinically relevant variables, including treatment group, baseline characteristics, and variables associated with the outcomes. Five imputed datasets were generated,

and the results were pooled for analysis. A complete-case (per-protocol) analysis including only participants with complete outcome data was performed as a sensitivity analysis. Categorical variables are presented as numbers or percentages and continuous variables with a normal distribution are reported as mean ± standard deviation (SD), whereas those with a non-normal distribution are presented as median (interquartile range [IQR]). Group comparisons were performed using the chi-square test or Fisher's exact test for categorical variables, and the independent t-test or Mann–Whitney U test for continuous variables, depending on the distribution. All statistical analyses were performed using IBM SPSS Statistics, version 22 (IBM Corp, Armonk, NY, USA). A *p*-value of less than 0.05 was considered statistically significant.

RESULTS

A total of 170 patients were randomized and included in the intention-to-treat analysis (Fig 1). Eight participants had missing outcome data due to insufficient observation time or protocol discontinuation. Missing outcome data were handled using multiple imputation. Baseline demographics (Table 1) and laboratory data (Table 2) were similar between the two groups. The primary diagnoses leading to CCU admission included acute myocardial infarction, heart failure, valvular heart disease and arrhythmia, with no significant differences between the two groups. However, the protocol group had a higher proportion of males than the usual care group (78.8% vs 64.7%, $p = 0.041$). Additionally, a history of stroke was more common in the usual care group than in the protocol group (9.4% vs 1.2%, $p = 0.034$).

Enema use was observed in 17.41% of patients in the protocol group and 16.45% in the usual care group. Constipation occurred in 25.41% and 36.94% of patients, respectively. The incidence of diarrhea was low in both groups (1.0% vs 1.2%). Patient satisfaction with bowel movements did not differ significantly between the groups ($p > 0.05$). A complete-case (per-protocol) analysis, performed as a sensitivity analysis, including 162 participants (80 in the protocol group and 82 in the usual care group) yielded similar results to the primary analysis (Table 3).

Further exploratory per-protocol analysis of bowel movement within 24 hours among the protocol subgroups showed that Group 2 had the highest rate (40.0%), followed by Group 1 (33.3%), while Group 3 had the lowest rate (2.2%). This difference was statistically significant ($p = 0.002$).

DISCUSSION

This study compared the effects of a constipation prevention and management protocol with usual care procedures on enema use, constipation, diarrhea, and patient satisfaction with defecation in critically ill cardiac patients. The results showed that enema administration and constipation rates tended to be lower in the protocol group than in the usual care group. These findings are consistent with previous studies evaluating constipation prevention and management protocols in critically ill patients.[12,13] However, this study differs from others in its use of the ROME criteria to assess bowel habits. Despite the use of the ROME criteria, the results are largely similar, likely due to common factors among cardiac patients, such as fluid restriction and the use of diuretic or calcium channel blockers, both of which are known to increase the risk of constipation.[8,16] Furthermore, the heterogeneity of underlying diseases among participants may have influenced the findings, as this study included eligible participants with various cardiac conditions, although no significant differences were observed between the groups.

A per-protocol analysis was conducted to compare three subgroups within the protocol group, further classified according to individual defecation behavior. As described previously, patients in Groups 1 and 2 had difficulty with defecation based on the ROME criteria and therefore received laxatives on the first day of admission. In contrast, patients in Group 3 had normal defecation patterns and received laxatives only if no bowel movement occurred within 48 hours after randomization. The results showed that patients in Group 3 had the lowest rate of bowel movements within 24 hours. However, this subgroup analysis was exploratory, and the study was not powered to detect differences among these subgroups. Therefore, these findings should be interpreted with caution and considered hypothesis-generating. Likewise, *Guardiola et al.* demonstrated that prophylactic laxative administration effectively reduced constipation in intensive care unit patients.[14] These findings support the idea that early constipation prevention and management protocols should include laxatives for all critically ill patients on the first day of admission. Furthermore, non-pharmacological strategies may also contribute to improving gastrointestinal motility. Chewing gum, considered a form of sham feeding, has been reported to stimulate vagal activity and facilitate earlier recovery of bowel function. Previous studies have shown that chewing gum combined with standard nursing care can reduce postoperative ileus and promote an earlier return of bowel

TABLE 1. Demographic and baseline characteristics of patients in the protocol and usual care groups.

Characteristics	Protocol group N = 85 (%)	Usual care group N = 85 (%)	*p* value
Age (mean ± SD)	65.2 ± 12.3	66.4 ± 13.7	0.540
Sex (male)	67 (78.8%)	55 (64.7%)	0.041*
Primary diagnosis			
MI		0.121	
STEMI	50 (58.8%)	49 (57.6%)	
NSTEMI	24 (28.2%)	16 (18.8%)	
Heart failure	13 (15.3%)	11 (12.9%)	0.660
Valvular heart disease	3 (3.5%)	5 (5.9%)	0.720
Arrhythmia	3 (3.5%)	9 (10.6%)	0.072
Underlying disease			
Diabetes mellitus	26 (31.0%)	30 (35.3%)	0.550
Hypertension	21 (25.0%)	13 (15.3%)	0.120
Dyslipidemia	19 (22.6%)	12 (14.1%)	0.150
Stroke	1 (1.2%)	8 (9.4%)	0.034*
Hypothyroid	1 (1.2%)	1 (1.2%)	1.000
Parkinson	2 (2.4%)	1 (1.2%)	0.620
Medications prior to admission			
Calcium channel blockers	7 (8.3%)	8 (9.5%)	0.790
Diuretic	4 (4.8%)	11 (13.1%)	0.058
Metformin	2 (2.4%)	0 (0.0%)	0.500
Iron supplements	6 (7.1%)	1 (1.2%)	0.12
Medications on admission			
Potassium Chloride Elixir	67 (81.7%)	59 (71.1%)	0.110
5% MgCl2 solution	2 (2.4%)	5 (6.0%)	0.440
Colchicine	1 (1.2%)	1 (1.2%)	1.000
Piperacillin/tazobactam inj.	3 (3.7%)	4 (4.8%)	1.000
Midazolam inj.	1 (1.2%)	1 (1.2%)	1.000
Fentanyl inj.	3 (3.7%)	4 (4.8%)	1.000
Morphine inj.	0	1 (1.2%)	1.000
Calcium polystyrene sulfonate	1 (1.2%)	2 (2.4%)	1.000
LOS (Day), median (IQR)	3 (2.0 - 4.0)	3 (2.0 - 4.0)	0.460

*$p < 0.05$

Abbreviations: Inj, injection; IQR, Interquartile Range; LOS, Length of stay; NSTEMI, non-ST-elevation myocardial infarction; SD, Standard Deviation; STEMI, ST-elevation myocardial infarction.

TABLE 2. Baseline laboratory results in the protocol and usual care groups.

Laboratory	Protocol group N = 85	Usual care group N = 85	*p* value
BUN (mg/dL)	15.2 (12.0 - 26.0)	17.5 (13.6 - 26.6)	0.130
Creatinine (mg/dL)	1.0 (0.8 - 1.6)	1.1 (0.8 - 1.4)	0.550
Sodium (mmol/L)	137.2 ± 3.4	137.3 ± 3.9	0.880
Potassium (mmol/L)	4.0 ± 0.5	3.9 ± 0.5	0.360
Chloride (mmol/L)	101.3 ± 4.0	101.8 ± 4.8	0.440
Bicarbonate (mmol/L)	21.7 ± 2.7	21.9 ± 3.6	0.750
Magnesium (mg/dL)	2.1 ± 0.3	2.1 ± 0.3	0.630
Phosphorus (mg/dL)	3.3 (2.9 - 3.9)	3.5 (3.2 - 3.9)	0.390
Ionized calcium (mg/dL)	6.4 ± 2.4	5.4 ± 1.9	0.110
Hematocrit (%)	39.7 ± 7.1	38.8 ± 6.0	0.380
Hemoglobin (g/dL)	13.0 ± 2.5	12.8 ± 2.1	0.520
White blood cells (x 10^3/μL)	10.065 (8.130 - 12.300)	10.720 (8.140 - 13.305)	0.510
Platelets (x 10^3/μL)	246.000 (194.000 -280.000)	226.000 (192.000 - 286.000)	0.640

Abbreviations: mg/dL, milligrams per deciliter; mmol/L, millimoles per liter; μL, microliter.

TABLE 3. Clinical outcomes according to ITT and per-protocol analyses.

Outcomes	Protocol group (ITT, N=85), %	Usual care group (ITT, N=85), %	*p* value	Protocol group (PP, N=80), %	Usual care group (PP, N=82), %	*p* value
Enema	17.41	16.45	-	15.00	17.10	0.719
Constipation	25.41	36.94	-	25.00	35.40	0.151
Diarrhea	1.00	1.20	-	0	1.20	1.000
Satisfaction with defecation (mean ± SD)	4.43± 0.09	4.27± 0.09	0.221	4.38± 0.64	4.27± 0.66	0.210

ITT results are presented as pooled percentages from multiple imputed datasets. P-values for some ITT outcomes were not reported because of instability of the pooled estimates across imputed datasets. PP analysis was conducted using complete-case data.
Abbreviations: ITT, intention-to-treat; PP, per-protocol; SD, Standard Deviation.

function.[17] Additionally, physical stimulation techniques such as abdominal massage have also been reported to enhance bowel movement and promote defecation in hospitalized patients. A study published in *Siriraj Medical Journal* demonstrated that Thai traditional abdominal massage improved defecation outcomes in patients following lumbar laminectomy.[18] In the present study, only one case of diarrhea occurred in the usual care group, with none in the protocol group. This lower incidence, compared to previous studies,[12,13] may be explained by shared clinical factors among cardiac patients, as previously discussed. Moreover, nearly half of the patients with constipation refused enema administration. This could be due to previous experiences of dissatisfaction, including embarrassment, anal pain, and abdominal cramps, among other factors.[19]

Patient satisfaction is a subjective measure and may be influenced by individual perceptions of the care received. To mitigate potential response bias, we standardized the administration procedure for both groups and assured participants that their responses would remain confidential and would not affect their medical care. In the present study, patient satisfaction with defecation was similar between the two groups. This finding may be related to the stigma and embarrassment associated with discussing defecation, leading to reluctance among patients to express their true feelings. Furthermore, with the division of the protocol group into three subgroups based on individual defecation behavior assessed via a questionnaire, some patients may have felt embarrassed about providing information openly,[20] leading to most patients being categorized into Group 3 (normal defecation). This possible misclassification may have resulted in Group 3 being contaminated with patients who should have been assigned to other groups.

The primary strength of this study is the application of the ROME criteria to evaluate constipation in acute cardiac patients, a population at high risk for bowel dysfunction. This standardized approach offers a foundation for future investigations on early bowel assessment and supports its integration into routine clinical practice. In addition, the study employed a randomized controlled design, with outcomes analyzed according to the intention-to-treat principle and missing data addressed using multiple imputation, which strengthens the validity of the findings. The protocol also highlights the important role of critical care nurses and physicians in delivering individualized bowel management.

Limitations

This study has several limitations. First, some participants had missing outcome data due to insufficient observation time or protocol discontinuation. Although multiple imputation was used to address missing data, residual bias cannot be completely excluded. However, consistent findings in sensitivity analyses support the robustness of the results. Second, the use of a Glasgow Coma Scale (GCS) score >8 as an inclusion criterion may not accurately capture the cognitive status of critically ill patients, who are often affected by sedation, delirium, or altered levels of consciousness. Incorporating validated assessment tools such as the Confusion Assessment Method for the ICU (CAM-ICU) and the Richmond Agitation-Sedation Scale (RASS) is recommended to improve cognitive evaluation and the reliability of outcomes. Third, the short median length of stay (three days) may have limited the ability to fully observe the development and progression of constipation, which frequently requires longer monitoring. Therefore, extended follow-up beyond ICU discharge is necessary to assess long-term outcomes. Future studies should also include post-transfer follow-up to evaluate delayed complications and the sustained effectiveness of the protocol.

CONCLUSIONS

This study found no significant differences between the protocol and usual care groups. Nevertheless, the use of the ROME criteria may assist physicians and nurses in assessing defecation patterns and guiding bowel management in critically ill cardiac patients.

Data Availability Statement

The datasets generated and analyzed during the current study are not publicly available due to ethical and privacy restrictions but are available from the corresponding author upon reasonable request.

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Conflict of Interest

The authors declare no conflict of interest regarding the publication of this paper.

Registration Number of Clinical Trial

TCTR20241114002

Author Contributions

Conceptualization, Validation, Visualization and Resources, P.S., C.D., S.K., P.W., and T.B.; Methodology, Formal analysis, Supervision, Writing – original draft, Writing – review & editing P.S., and T.B; Investigation, P.S., C.D., S.K., and P.W.; Data curation, P.S., C.D., and S.K.; Project administration, P.S. All authors have read and agreed to the final version of the manuscript.

Use of Artificial Intelligence

The authors acknowledge the use of ChatGPT (https://chatgpt.com/) for translation and grammar checking during manuscript preparation. The authors have thoroughly reviewed and revised the content where necessary and accept full responsibility for the final version of the manuscript.

Ethics Approval

This study was reviewed and approved by the Institutional Review Board (COA No. Si539/2021). All patients provided written informed consent prior to participation.

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