

Clinical significance of the timing of high-output stoma onset after ileostomy: Association with stoma outlet obstruction and length of hospital stay

Takuya Shiraishi

tashirai@gunma-u.ac.jp

Gunma University

Yuji Nishizawa

National Cancer Center Hospital East

Mifumi Nakajima

National Cancer Center Hospital East

Ryoko Kado

National Cancer Center Hospital East

Hiroomi Ogawa

Gunma University

Naomi Satoh

Gunma University Hospital

Yohei Owada

University of Tsukuba

Tsuyoshi Enomoto

University of Tsukuba

Shinji Yazawa

University of Tsukuba

Yukihiro Hamahata

Tsujinaka Hospital Kashiwanoha

Yumi Isogami

Tsujinaka Hospital Kashiwanoha

Kazuo Kitagawa

Jikei University Kashiwa hospital

Maki Sakamoto

Jikei University Kashiwa hospital

Hiroya Enomoto

The Jikei University Daisan Hospital

Akiko Egawa

The Jikei University Hospital

Daichi Kitaguchi

National Cancer Center Hospital East

Hiro Hasegawa

National Cancer Center Hospital East

Koji Ikeda

National Cancer Center Hospital East

Yuichiro Tsukada

National Cancer Center Hospital East

Masaaki Ito

National Cancer Center Hospital East

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Abstract

Purpose

To evaluate whether the timing of high-output stoma (HOS) onset is associated with stoma outlet obstruction (SOO) and postoperative clinical burden after ileostomy.

Methods

In this prospective, multicenter observational study, we screened 217 patients with malignant rectal tumors who underwent surgery with stoma formation between December 2019 and December 2021. Ultimately, 117 patients who underwent ileostomy were included in the analysis. Early HOS was defined as HOS occurring on or before postoperative day (POD) 5, whereas late HOS was defined as HOS occurring on or after POD 6. The risk of SOO and the diagnostic performance of HOS timing were assessed.

Results

Of the 117 patients, 34 developed early HOS, 8 developed late HOS, and 75 did not develop HOS. SOO incidence increased stepwise from the no-HOS group to the early and late HOS groups (5.3%, 14.7%, and 37.5%, respectively; $p = 0.010$). Compared with no HOS, the relative risk of SOO was 3.57 for any HOS ($p = 0.027$), 2.76 for early HOS ($p = 0.134$), and 7.03 for late HOS ($p = 0.018$). Hospital stay was significantly longer in the late HOS group than in the early and no-HOS groups ($p = 0.002$). Late HOS demonstrated low sensitivity (25.0%) but high specificity (95.2%) and a positive likelihood ratio of 5.25 for predicting SOO.

Conclusions

SOO incidence increased stepwise from no HOS to early and late HOS. HOS timing may reflect the degree of obstruction-related pathophysiology after ileostomy and late HOS may serve as a practical clinical indicator of underlying SOO rather than as a screening marker.

Introduction

Temporary ileostomy is commonly performed during surgery for malignant rectal tumors to protect low colorectal or coloanal anastomoses and mitigate the clinical consequences of anastomotic leakage. Despite its important role in perioperative management, ileostomy is associated with dehydration, electrolyte imbalance, renal dysfunction, and stoma-related complications [1–4]. Among these complications, high-output stoma (HOS) is a clinically important condition that complicates patient management from the early postoperative period through discharge. It often necessitates prolonged

fluid replacement, dietary modification, pharmacologic therapy, and, in some cases, hospital readmission [1–3, 5]. HOS is multifactorial in origin and has been attributed to bowel edema, recovery of intestinal motility, increased intestinal secretion, impaired absorption, and infectious complications [6–8].

Increasing attention has recently been directed toward the association between HOS and stoma outlet obstruction (SOO) [8]. SOO is a stoma-related complication characterized by impaired intestinal passage at the stoma outlet, which may result from relative narrowing of the abdominal wall, kinking of the stoma limb, or bowel edema. Clinically, patients with SOO may present with abdominal distension, pain, nausea, vomiting, and reduced stoma output. Symptoms often improve following trans-stomal catheter insertion, suggesting that mechanical or functional obstruction at the level of the abdominal wall is central to the pathophysiology of SOO [9]. However, SOO does not always present as a complete obstruction. In cases of partial obstruction or relative narrowing, proximal bowel dilatation and increased intraluminal pressure may paradoxically increase stoma output [8, 10]. Therefore, HOS may reflect excessive fluid loss while also indicating underlying SOO or obstruction-related pathophysiology.

The relationship between HOS and SOO may vary according to the timing of HOS onset. Early postoperative HOS may reflect transient physiological changes, including postoperative bowel edema, perioperative fluid shifts, and recovery of intestinal motility. In contrast, HOS developing later in the postoperative course may indicate structural or inflammatory conditions, including abdominal wall obstruction, kinking of the stoma limb, intra-abdominal infection, or inflammatory ileus. Accordingly, classifying HOS by the timing of onset, rather than evaluating it as a single entity, may facilitate identification of the underlying pathophysiology, including SOO, and guide further diagnostic evaluation.

Previous studies have investigated the incidence of HOS and its association with dehydration, renal dysfunction, readmission, and SOO. However, most studies have evaluated HOS as a binary outcome, and evidence regarding the association between the timing of HOS onset and SOO remains limited. We hypothesized that the incidence of SOO would increase progressively according to the timing of HOS onset, reflecting a gradual enrichment of obstruction-related pathophysiology from no HOS to early HOS and, ultimately, late HOS. Accordingly, this study aimed to clarify the clinical significance of HOS timing and to determine whether the stepwise increase in SOO incidence supports the concept of an obstruction-related postoperative phenotype following ileostomy. Our findings may improve the early recognition of patients at risk for SOO and support timely diagnostic evaluation and appropriate management.

Methods

Study design and patients

This prospective, multicenter observational cohort study was conducted at six high-volume regional hospitals in Japan between December 2019 and December 2021. Patients with malignant rectal tumors

scheduled to undergo surgical procedures involving stoma formation at the participating institutions were eligible for enrollment.

The inclusion criteria were: (i) histologically confirmed malignant rectal tumor, including adenocarcinoma; (ii) surgical treatment with temporary stoma formation; (iii) any clinical stage; (iv) primary or recurrent disease; (v) age ≥ 20 years at enrollment; (vi) ileostomy creation; and (vii) provision of written informed consent for observational data collection. The exclusion criteria were: (i) missing essential data regarding stoma output or stoma-related complications; (ii) development of HOS or SOO after discharge; (iii) inability to complete scheduled assessments according to the study protocol or; (iv) being considered unsuitable for analysis by the investigators.

This study was conducted in accordance with the ethical principles of the Declaration of Helsinki. The study protocol, participant information sheet, and informed consent forms were approved by the Ethics Committee of the National Cancer Center East Hospital (Approval No. 2019 – 204) and the institutional review boards of all participating institutions. Written informed consent was obtained from all participants before enrollment.

Assessment of stoma output and stoma-related complications

Stoma-related assessments were performed by experienced wound, ostomy, and continence nurses and colorectal surgeons. To ensure consistency across participating institutions, a standardized evaluation manual was distributed across all six hospitals before study initiation.

During the index hospitalization, ward nurses measured the stoma output several times daily, and the total daily stoma output was calculated for each patient. HOS was defined as a daily stoma output exceeding 1,500 mL or a clinical condition requiring treatment for dehydration attributable to excessive stoma output [3, 6]. The postoperative day (POD) on which the maximum daily stoma output was recorded was defined as the maximum stoma output, regardless of whether HOS developed.

Patients were classified into three groups according to the timing of HOS onset: early, late, and no HOS. Early HOS was defined as HOS occurring on or before POD 5, whereas late HOS was defined as HOS occurring on or after POD 6. POD 5 was selected as a clinically pragmatic cutoff to distinguish the immediate postoperative phase from the later postoperative phase. This cutoff was based on previous studies indicating that ileostomy output generally begins to decrease approximately 5 days after stoma formation [5]. During the immediate postoperative phase, transient physiological changes, including bowel edema, perioperative fluid shifts, and recovery of intestinal motility, may influence stoma output. In contrast, after POD 6, oral intake generally progresses, and structural or inflammatory complications, including SOO and intra-abdominal infection, become more clinically apparent. Patients who did not meet the criteria for HOS during the index hospitalization were classified into the no-HOS group.

SOO was defined as an obstruction at the abdominal wall level of the ileostomy, typically accompanied by symptoms or findings of impaired stoma outflow and improvement following trans-stomal catheter

insertion through the efferent or functional limb of the stoma [8]. Only SOO diagnosed during the index hospitalization was included in the present analysis.

Variables and outcomes

Baseline variables included sex, age, body mass index, current smoking status, diabetes mellitus, hypertension, cardiovascular disease, preoperative treatment, preoperative laboratory data, surgical approach, stoma type, and stoma height. Laboratory variables included hemoglobin, albumin, creatinine, glutamic oxaloacetic transaminase, and glutamic pyruvic transaminase levels.

The primary objective of this analysis was to evaluate the association between the timing of HOS onset and SOO. Clinical outcomes included maximum stoma output, the POD of maximum stoma output, acute kidney injury, SOO, infectious complications, and length of hospital stay. We also compared the risk of SOO across the HOS timing groups using relative risk (RR) estimates, and the diagnostic performance of HOS timing for predicting SOO was evaluated.

Statistical analysis

Continuous variables are presented as medians with ranges, and categorical variables are presented as numbers and percentages. Continuous variables were compared among the early, late, and no-HOS groups using the Kruskal–Wallis test. Categorical variables were compared using the chi-square test or Fisher's exact test, as appropriate. The risk of SOO was evaluated using the no-HOS group as the reference. RRs and 95% confidence intervals (CIs) were calculated for any, early, and late HOS. Pairwise comparisons between each HOS group and the no-HOS group were performed using Fisher's exact test.

To evaluate the utility of HOS timing as a clinical indicator of SOO, the sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio, and negative likelihood ratio were calculated for any, early, and late HOS. Multivariable regression analysis was not performed, as the number of SOO events was limited. All statistical analyses were performed using SPSS Statistics version 29.0 (IBM Corp., Armonk, NY, USA). Two-sided $p < 0.05$ was considered statistically significant.

Results

Patient selection

Between December 2019 and December 2021, 217 patients were screened for eligibility for this study. After excluding 100 patients, including 9 without stoma formation, 45 with colostomy, and 46 with insufficient data on stoma output or stoma-related complications, 117 patients who underwent ileostomy were included in the final analysis (Fig. 1).

Patient characteristics according to HOS timing

A total of 117 patients who underwent ileostomy were included in the analysis. Early HOS occurred in 34 patients, whereas late HOS occurred 8 patients. The remaining 75 patients did not develop HOS.

Patient characteristics according to the timing of HOS are summarized in Table 1. No significant differences in sex, age, body mass index, current smoking status, diabetes mellitus, hypertension, cardiovascular disease, or preoperative treatment were observed among the early, late, and no-HOS groups. Preoperative laboratory parameters, including hemoglobin, albumin, creatinine, glutamic oxaloacetic transaminase, and glutamic pyruvic transaminase levels, were also comparable among the three groups. Although the surgical approach differed significantly among the groups ($p = 0.045$), only two patients underwent open surgery. Stoma type and height did not differ significantly among the groups.

Table 1
Patient characteristics according to HOS timing

Sex		Early HOS (POD ≤ 5), n = 34	Late HOS (POD ≥ 6), n = 8	No HOS, n = 75	p-value
	Male	29 (85.3)	6 (75.0)	50 (66.7)	0.128
	Female	5 (14.7)	2 (25.0)	25 (33.3)	
Age, years		60.0 (34.0–81.0)	69.5 (40.0–83.0)	67.0 (23.0–82.0)	0.746
BMI, kg/m ²		22.9 (17.4–31.2)	20.6 (17.3–27.5)	23.9 (15.7–31.2)	0.406
Current smoking status	Non-current smoker	25 (73.5)	7 (87.5)	60 (80.0)	0.611
	Current smoker	9 (26.5)	1 (12.5)	15 (20.0)	
Diabetes mellitus		2 (5.9)	1 (12.5)	13 (17.3)	0.271
Hypertension		12 (35.3)	4 (50.0)	22 (29.3)	0.454
Cardiovascular disease		2 (5.9)	0 (0.0)	6 (8.0)	0.672
Preoperative treatments		10 (29.4)	2 (25.0)	22 (29.3)	0.966
Hb (g/dL)		13.5 (10.0–18.1)	13.5 (9.5–14.5)	13.5 (8.2–16.6)	0.794
Alb (g/dL)		4.2 (2.9–4.7)	4.2 (2.6–4.8)	4.2 (2.5–5.1)	0.708
Cr (mg/dL)		0.79 (0.47–1.29)	0.86 (0.52–1.09)	0.78 (0.20–1.80)	0.964
GOT (IU/L)		17.0 (13.0–42.0)	21.5 (17.0–34.0)	20.0 (11.0–53.0)	0.184
GPT (IU/L)		16.0 (9.0–57.0)	17.0 (14.0–32.0)	19.0 (7.0–56.0)	0.541
Approach type	Open	0 (0.0)	1 (12.5)	1 (1.3)	0.045
	Lap or Rob	34 (100.0)	7 (87.5)	74 (98.7)	
Stoma type	End	0 (0.0)	0 (0.0)	1 (1.3)	0.754
	Loop	34 (100.0)	8 (100.0)	74 (98.7)	

Sex	Early HOS (POD ≤ 5), n = 34	Late HOS (POD ≥ 6), n = 8	No HOS, n = 75	p-value
Male	29 (85.3)	6 (75.0)	50 (66.7)	0.128
Height of stoma	13.5 (4.0–30.0)	10.5 (5.0–30.0)	13.0 (0.0–33.0)	0.237

Lap, laparoscopic; Rob, robotic; Hb, hemoglobin; Alb, albumin; Cr, creatinine; BMI, body mass index; HOS, high-output stoma; POD, postoperative day; GOT, glutamic oxaloacetic transaminase; GPT, glutamic pyruvic transaminase

Clinical outcomes according to HOS timing

Clinical outcomes according to HOS timing are presented in Table 2. Maximum stoma output differed significantly among the three groups, and was higher in the early and late HOS groups than in the no-HOS group (early HOS, 2,380 mL/day [range, 1,580–5,650 mL/day]; late HOS, 2,285 mL/day [range, 1,740–2,780 mL/day]; no HOS, 910 mL/day [range, 200–1,480 mL/day]; $p < 0.001$). The POD on which the maximum stoma output was recorded also differed significantly among the groups (early HOS, POD 3.0 [range, 2.0–11.0]; late HOS, POD 8.5 [range, 6.0–15.0]; no HOS, POD 6.0 [range, 1.0–22.0]; $p < 0.001$).

Table 2
Clinical outcomes according to HOS timing

Maximum stoma output, mL/day	Early HOS (POD ≤ 5), n = 34	Late HOS (POD ≥ 6), n = 8	No HOS, n = 75	p-value
	2,380 (1,580–5,650)	2,285 (1,740–2,780)	910 (200–1,480)	< 0.001
Maximum stoma output POD	3.0 (2.0–11.0)	8.5 (6.0–15.0)	6.0 (1.0–22.0)	< 0.001
Acute kidney injury, n (%)	0 (0.0)	0 (0.0)	1 (1.3)	0.754
Stoma outlet obstruction, n (%)	5 (14.7)	3 (37.5)	4 (5.3)	0.010
Infectious complications, n (%)	3 (8.8)	2 (25.0)	6 (8.0)	0.291
Length of hospital stay, days	13.0 (9.0–46.0)	25.0 (13.0–51.0)	12.0 (7.0–35.0)	0.002
Notes: Maximum stoma output POD indicates the POD on which the maximum daily stoma output was recorded, regardless of whether HOS developed				
HOS, high-output stoma; POD, postoperative day				

The incidence of SOO increased progressively from the no-HOS group to the early and late HOS groups. SOO occurred in four patients without HOS (5.3%), five patients with early HOS (14.7%), and three patients with late HOS (37.5%) ($p = 0.010$). Acute kidney injury was rare and did not differ significantly among the groups. Infectious complications occurred more frequently in the late HOS group than in the early and no-HOS groups, although the difference was not statistically significant (25.0% vs. 8.8% and 8.0%, respectively; $p = 0.291$). The length of hospital stay was significantly longer in the late HOS group than in the early and no-HOS groups (late HOS, 25.0 days [range, 13.0–51.0]; early HOS, 13.0 days [range, 9.0–46.0]; no HOS, 12.0 days [range, 7.0–35.0]; $p = 0.002$) (Fig. 2).

Risk of SOO according to HOS timing

The risk of SOO according to HOS timing is presented in Table 3. Compared with patients without HOS, patients with any HOS had a significantly higher risk of SOO (19.0% vs 5.3%; RR, 3.57; 95% CI, 1.14–11.16; $p = 0.027$). Classification of HOS by the timing of onset revealed a stepwise increase in the incidence of SOO from the no-HOS group to the early and late HOS groups. Early HOS was associated with a numerically higher risk of SOO than no HOS, although the difference was not statistically significant (14.7% vs. 5.3%; RR, 2.76; 95% CI, 0.79–9.63; $p = 0.134$). Late HOS was associated with the highest incidence of SOO and a significantly higher risk of SOO than no HOS (37.5% vs. 5.3%; RR, 7.03; 95% CI, 1.90–25.99; $p = 0.018$). This gradient in SOO incidence supports the hypothesis that the timing of HOS may reflect the degree of obstruction-related pathophysiology following ileostomy.

Table 3
Risk of SOO according to HOS timing

Comparison	SOO/ total	SOO rate (%)	Relative risk	95% CI	<i>p</i> -value
No HOS	4/ 75	5.3	Reference	—	—
Any HOS	8/ 42	19.0	3.57	1.14–11.16	0.027
Early HOS (POD ≤ 5)	5/ 34	14.7	2.76	0.79–9.63	0.134
Late HOS (POD ≥ 6)	3/ 8	37.5	7.03	1.90–25.99	0.018

HOS, high-output stoma; POD, postoperative day; CI, confidence interval; SOO, stoma outlet obstruction

Diagnostic performance of HOS timing for predicting SOO

The diagnostic performance of HOS timing for predicting SOO is summarized in Table 4. Overall, HOS demonstrated moderate sensitivity of 66.7% and specificity of 67.6% for identifying SOO, with a positive predictive value of 19.0%, negative predictive value of 94.7%, positive likelihood ratio of 2.06, and negative likelihood ratio of 0.49.

Early HOS showed limited diagnostic performance for identifying SOO, with a sensitivity of 41.7%, specificity of 72.4%, positive predictive value of 14.7%, negative predictive value of 91.6%, positive likelihood ratio of 1.51, and negative likelihood ratio of 0.81. In contrast, late HOS demonstrated low

sensitivity of 25.0% but high specificity of 95.2% for SOO prediction, with a positive predictive value of 37.5%, negative predictive value of 91.7%, positive likelihood ratio of 5.25, and negative likelihood ratio of 0.79. These findings suggest that late HOS may be more useful as a specific clinical indicator of underlying SOO than as a screening marker.

Table 4
Diagnostic performance of HOS timing for predicting stoma outlet obstruction

Indicator	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	LR+	LR-
Any HOS	66.7	67.6	19.0	94.7	2.06	0.49
Early HOS (POD $\leq$ 5)	41.7	72.4	14.7	91.6	1.51	0.81
Late HOS (POD $\geq$ 6)	25.0	95.2	37.5	91.7	5.25	0.79

HOS, high-output stoma; POD, postoperative day; PPV, positive predictive value; NPV, negative predictive value; LR, likelihood ratio

Discussion

This study focused on the timing of HOS onset after ileostomy creation and compared the clinical outcomes among patients with early, late, and no HOS. The principal finding was a stepwise increase in the incidence of SOO according to HOS timing, from 5.3% in patients without HOS, 14.7% in patients with early HOS, and 37.5% in patients with late HOS. Late-onset HOS was also associated with a significantly longer hospital stay. Furthermore, although late HOS demonstrated low sensitivity for predicting SOO, it exhibited high specificity and a high positive likelihood ratio. These findings suggest that the timing of HOS may reflect a progressive increase in obstruction-related pathophysiology and that late HOS may serve as a clinical indicator of underlying SOO rather than as a broad screening marker.

A key implication of this study is that HOS should not be regarded solely as a binary condition. Traditionally, HOS has been recognized as a postoperative complication associated with dehydration, electrolyte imbalance, renal dysfunction, and hospital readmission [1–4]. However, HOS likely represents heterogeneous pathophysiological conditions, ranging from transient and functional increases in stoma output during the early postoperative period to structural or inflammatory conditions associated with SOO or infectious complications [8]. In the present study, the SOO rate increased progressively from the no-HOS group to the early and late HOS groups. This gradient, rather than the statistical significance of late HOS alone, is clinically meaningful, as it supports the hypothesis that the timing of HOS onset reflects the degree of obstruction-related pathophysiology.

The POD 5 cutoff should not be interpreted as a strict biological threshold but rather as a pragmatic clinical boundary to distinguish early transient postoperative changes from later events potentially related to obstruction or inflammation. Ileostomy output generally begins to decrease approximately 5 days after stoma formation [5]. Therefore, HOS occurring on or before POD 5 likely reflected immediate

postoperative physiological changes, whereas HOS occurring on or after POD 6 more likely reflected later postoperative events, including SOO or inflammatory complications.

The pathophysiological differences between early and late HOS may be explained by the anatomical and physiological changes occurring during the postoperative course. Early HOS (POD1–POD 5) may primarily reflect edema of the stoma limb or abdominal wall tunnel, postoperative third-space fluid shifts, perioperative fluid administration, recovery of intestinal motility, and impaired absorptive capacity [6]. During this period, stoma output is typically watery, and even in the presence of mild narrowing or kinking at the level of the abdominal wall, clinically apparent obstruction may not develop as long as the effluent can pass through the stoma. In addition, early HOS may include patients with SOO, as well as those with transient, functionally increased stoma output that resolves without interventions such as trans-stomal catheter insertion. This may explain why early HOS was associated with a numerically higher incidence of SOO than no HOS but demonstrated limited specificity as a clinical indicator of SOO.

Meanwhile, late HOS (on or after POD 6) develops after the initial physiological postoperative changes begin to resolve and as ambulation and oral intake progress. During this period, the diet typically advances from liquids to soft or regular foods, resulting in increased viscosity of the intestinal contents. If subtle narrowing at the abdominal wall level or mild kinking of the stoma limb is present, intestinal contents that passed readily during the early phase of watery output may become more difficult to evacuate as viscosity increases, ultimately manifesting clinically as SOO [11, 12]. Moreover, partial luminal obstruction may lead to proximal bowel dilatation, increased intraluminal pressure, enhanced intestinal secretion, and reduced absorptive time, which may present as increased watery stoma output [5, 12]. Therefore, late HOS should not be interpreted simply as an idiopathic hypersecretory state but rather as a clinical phenotype reflecting underlying SOO or SOO-related mechanical or functional impairment of intestinal passage.

Inflammatory conditions may also contribute to the association between late HOS and SOO. Anastomotic leakage, pelvic abscess, and organ/space surgical site infections often become clinically apparent after approximately POD 5–7 or later [13, 14]. These inflammatory complications may cause bowel edema, inflammatory ileus, and relative narrowing of the abdominal wall, contributing to SOO or SOO-like passage disturbances. HOS and SOO are closely related major complications of diverting ileostomies and may share common pathophysiological mechanisms mediated by infection and inflammation [8]. In the present study, the incidence of infectious complications did not differ significantly among the groups; however, it was numerically higher in the late HOS group (25.0%). Clinically, the development of late HOS should prompt evaluation for SOO, together with assessment for intra-abdominal infection using imaging modalities such as computed tomography.

When considering the relationship between SOO and HOS, SOO should not be regarded solely as a complete obstruction. In clinical practice, SOO may present as relative narrowing at the abdominal wall level or as a partial passage disturbance around the stoma, with symptoms often improving after trans-stomal decompression [9, 15, 16]. Previous studies have reported a higher maximum stoma output in

patients with SOO, suggesting that partial passage disturbances may coexist with increased stoma output [12]. From this perspective, the stepwise increase in SOO incidence according to HOS timing may represent a clinical continuum in which obstruction-related and secretory mechanisms become progressively more prominent from no HOS to early HOS and ultimately to late HOS.

In this study, late HOS was associated with a significantly prolonged hospital stay. This finding suggests that late HOS is not merely characterized by increased stoma output but may represent a pathological phenotype requiring additional fluid management, dietary modification, imaging evaluation, trans-stomal intervention for SOO, and assessment and treatment of infectious complications [17, 18]. In contrast, no significant difference was observed in the length of hospital stay between the early and no-HOS groups, suggesting that early HOS may represent transient postoperative changes, whereas late HOS may indicate a more complicated postoperative course. Therefore, when HOS occurs, clinicians should consider not only the volume of stoma output but also the timing of its onset.

The clinical relevance of distinguishing late HOS from early HOS was further supported by the diagnostic performance analysis. In the present study, late HOS demonstrated low sensitivity for predicting SOO but high specificity (95.2%) and a positive likelihood ratio of 5.25, indicating an increased probability of SOO in the presence of late HOS. Therefore, late HOS should not be considered a screening marker for SOO but rather a clinical indicator prompting evaluation for SOO or SOO-related obstruction-associated pathophysiology. Clinically, when new-onset HOS occurs on or after POD 6, management should not be limited to fluid replacement, antidiarrheal therapy, and dietary modification. Instead, clinicians should evaluate for underlying conditions such as SOO and intra-abdominal infection and consider further diagnostic assessment using abdominal computed tomography.

This study has some limitations. First, the late HOS group included only eight patients, resulting in wide CIs for the estimated effect sizes. Therefore, the association between late HOS and SOO should be interpreted with caution due to the potential for random error and overestimation of the effect size. Second, only 12 patients developed SOO, precluding multivariable adjustment for potential confounders. Consequently, the influence of potential confounding factors, including patient characteristics, surgical approach, postoperative management, and infectious complications, cannot be fully excluded. Third, the surgical approach differed among the groups at baseline. Although open surgery was performed in only two patients—one in the late HOS group and one in the no-HOS group—and its impact on the present findings was likely limited, the potential influence of open versus minimally invasive surgery on HOS, SOO, postoperative bowel motility, and length of hospital stay cannot be completely ruled out. Fourth, this study included only HOS and SOO events occurring during the index hospitalization, and events developing after discharge were not evaluated. Consequently, selection bias may have been introduced by excluding post-discharge cases. In particular, post-discharge HOS or SOO may differ from in-hospital events in terms of pathophysiology and severity. Therefore, the present findings should be interpreted as reflecting HOS and SOO characteristics observed during hospitalization. Exclusion of post-discharge events may have also led to an underestimation of the overall incidence of HOS and SOO. Conversely, because post-discharge events may include milder cases that can be managed in an outpatient setting,

restricting the analysis to in-hospital events may have enriched the study population for more severe cases or those associated with prolonged hospitalization. Fifth, although stoma output was measured using a standardized method, the effects of dietary intake, fluid administration, antidiarrheal medication, prokinetic agents, and postoperative management protocols could not be fully controlled. Specifically, variations among participating institutions or attending physicians in the timing of diet advancement and initiation of fluid or pharmacologic therapy may have influenced both the timing of HOS onset and maximum stoma output. Finally, although this was a subanalysis of a prospective multicenter observational study, the original study was not specifically designed to classify HOS according to the timing of onset. Further large-scale prospective studies incorporating continuous post-discharge monitoring of stoma output, detailed postoperative management data, and standardized diagnostic criteria for SOO are warranted.

In conclusion, the incidence of SOO increased stepwise from no HOS to early and late HOS, suggesting that HOS timing may reflect the degree of obstruction-related pathophysiology following ileostomy. Although late HOS was relatively uncommon, it was associated with the highest incidence of SOO and prolonged hospitalization and may serve as a practical clinical indicator of underlying conditions such as SOO or intra-abdominal infection. Rather than evaluating HOS as a single entity, assessment according to the timing of onset may facilitate earlier recognition of SOO, guide appropriate diagnostic evaluation, and optimize postoperative management.

Declarations

Funding and/or competing interests: No funding was received for this study. The authors declare that they have no competing interests.

Ethical approval statement: This study was approved by the Ethics Committee of the National Cancer Center East Hospital (Approval No. 2019-204) and by the institutional review boards of all participating institutions.

Consent to participate: Written informed consent was obtained from all participants before enrollment.

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Data availability statement: The datasets used and/or analyzed during the current study available from the corresponding author on reasonable request.

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Figures

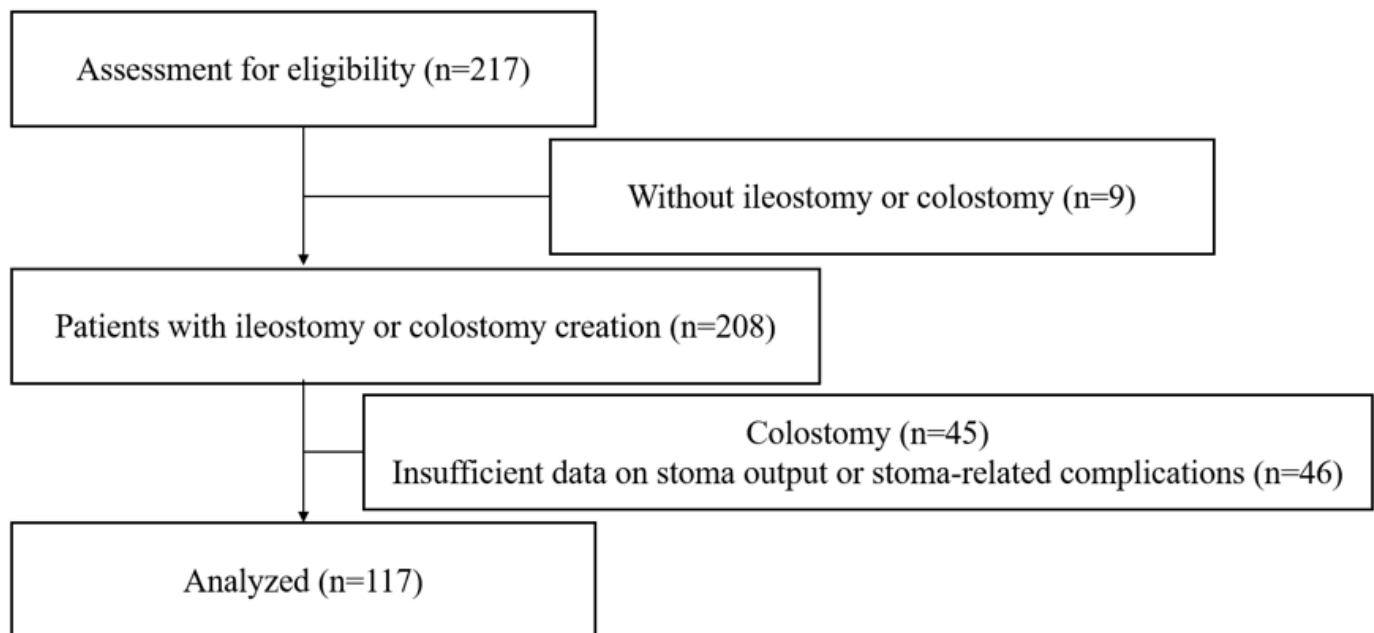


Figure 1

Flow diagram of patient selection

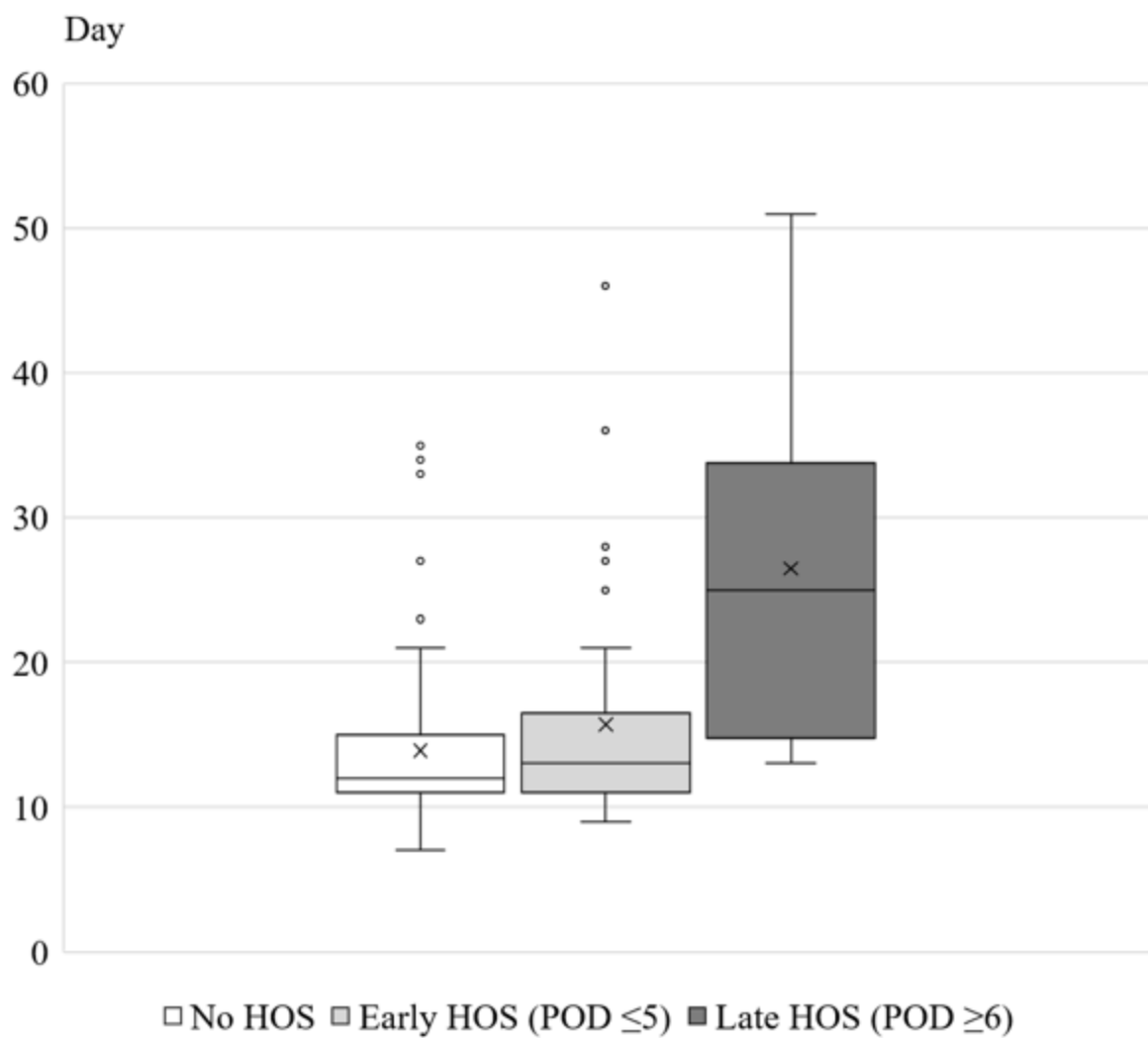


Figure 2

Length of the hospital stay according HOS timing

Data are presented as medians with ranges

HOS, high-output stoma; POD, postoperative day