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A predictive tool for postoperative ileus after ileostomy closure: Model development and validation

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ABSTRACT

Objecitve: Postoperative ileus (POI) is a significant complication after ileostomy closure, which results in recurrent vomiting, dehydration, delay in starting enteral feeding, and even anastomotic breakdown. We aimed to develop a prediction model for POI occurrence after ileostomy closure.

Material and Methods: One hundred consecutive patients undergoing ileostomy closure were studied prospectively and data of various demographic and clinical variables were recorded in a predesigned proforma. The final prediction model was developed using logistic regression and internally validated in the next 50 patients.

Results: Factors associated with POI were age, body mass index, tobacco or alcohol addiction, comorbidity, anemia, thrombocytopenia, renal dysfunction, as shown by creatinine level, hypoproteinemia, hypernatremia, and hypokalemia. The mean score of those who developed POI was higher (p=0.002) than those who did not. A cut-off at score 8 had a sensitivity of 85.71%, specificity of 73.12%, and area under the curve was 0.8241 (SE 0.1123). The predictive model was validated in the next 50 consecutive patients and showed good sensitivity (80%) and specificity (93.3%).

Conclusion: Our predictive model can determine the occurrence of POI with accuracy.

Keywords: Ileostomy, ileostomy closure, stoma reversal, postoperative ileus, prediction model

INTRODUCTION

Defunctioning ileostomy (DI) is often performed after major elective colorectal surgeries or emergency surgeries involving the small intestine. Although considered a safety net, DI is not without its share of complications (1). Similarly, closure of DI is also associated with its own complications and even mortality (2-4). Postoperative ileus (POI), defined as delayed return of bowel activity for >3 days, is an important complication occurring in up to 4-20% of patients after DI closure (4-8). This may lead to vomiting, abdominal distention, delay in starting enteral feeds, and the risk of anastomotic disruption, and it is reported to be the most common cause of readmission within 30 days. Preventing POI is important given its associated morbidity and increased cost of care.

Many per-operative factors have been found to be associated with POI after ileostomy closure (8-14). However, there is a scarcity of studies from low- and middle-income countries (LMICs). This prompted us to study probable risk factors for POI and to develop and validate a prediction model for POI.

MATERIAL and METHODS

This study was conducted in the department of surgery of a tertiary teaching hospital in central India from September 2019 to December 2022. It was approved by the Institutional Ethics Committee of Netaji Subhash Chandra Bose Medical College Jabalpur (M.P.) (no: IEC/2019/9906, date: 09.12.2019).

Patients presenting for DI reversal, irrespective of the indication for creation, were prospectively enrolled in this study. Patients were optimized for fitness for surgery before planning closure of stoma. Patients with malignancy received either adjuvant chemotherapy or radiotherapy before closure.

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Prior to closure, a distal loop contrast study was performed to rule out any distal obstruction or leak. Preoperatively, distal loop wash was given with normal saline and enema administered rectally to clear off any inspissated mucus and fecoliths. Patient variables were recorded in a predesigned proforma and their association with POI was noted (Table 1).

All ileostomy closures were performed using the hand-sewn technique in two layers with silk 2-0 round body sutures by consultants. All patients received a dose of first-generation cephalosporin preoperatively as prophylaxis. A 32G intraperitoneal drainage tube was inserted in all patients, which was removed between the fifth and sixth post-operative days (POD).

Standard enhanced recovery after surgery protocols were applied during the post-operative period. Patients were observed for development of bowel sounds, time to start of liquid diet and progression to solids, development of vomiting, abdominal distention, or other complications like surgical site infection (SSI) and leak.

POI was defined as delay in the occurrence of intestinal motility presenting as an intolerance to oral food in absence of clinical or radiological signs of obstruction on or after POD 3 that either (a) required nasogastric tube insertion; or (b) was associated with two of the following: Nausea/vomiting, abdominal distention or the absence of flatus (4,8,13).

Statistical Analysis

Statistical analysis was done using SPSS (IBM Corp. Released 2023. IBM SPSS Statistics for Windows, Version 29.0.2.0 Armonk, NY: IBM Corp).

Data analysis involved first univariate analysis to determine whether the variable has a significant effect on the outcome. These significant variables were later involved in multivariate regression analysis to determine the best combination of

Table 1. Patient variables, lab parameters and significance of their association with POI

Parameter		Total (n=100)	Non-POI (n=93)	Paralytic ileus (n=7)	p-value
Age	≤60 yrs	96	89	7	0.7466 (NS)
	>60 yrs	4	4	0	
Gender	Male	67	64	3	0.1601 (NS)
	Female	33	29	4	
BMI	≤18.5	28	23	5	0.0175 (S)
	>18.5	72	70	2	
Addiction	Alcohol	30	25	5	0.0242 (S)
	Tobacco/smoking	26	25	1	0.4133 (NS)
Comorbidity	Hypertension	5	5	0	0.6903 (NS)
	Diabetes	4	2	2	0.0237 (S)
	Tuberculosis	9	4	5	0.0001 (S)
	Chronic obstructive pulmonary disease	12	11	1	1 (NS)
	Any comorbidity	21	15	6	0.0014 (S)
	No comorbidity	79	78	1	
Nature of disease	Benign	87	80	7	0.5899 (NS)
	Malignant (adjuvant chemo/ radiotherapy)	13	13	0	
Pathology	Obstruction	53	48	5	0.4424 (NS)
	Perforation	47	45	2	
Duration before closure	≤3 months	35	33	2	1 (NS)
	>3 months	65	60	5	
SSI		17	10	7	0.0001
PONV		7	1	6	0.0001 (S)
Hospital stay during index surgery	≤10 days	92	90	2	0.0001 (S)
	>10 days	5	0	5	
Death		5	2	3	0.0012 (S)

POI: Postoperative ileus, BMI: Body mass index, SSI: Surgical site infection, PONV: Post-operative nausea and vomiting variables. Their cut-off values were determined using receiver operating characteristic (ROC) curves. The weighting scores were assigned to each variable based on its contribution in the multivariate analysis. The final score and cut-off were again determined using the ROC curve and a predictive tool was developed after performing multivariate analysis with various combinations of the above factors.

This predictive model was then subjected to validation in the next cohort of patients.

RESULTS

One hundred consecutive patients presenting for DI reversal were prospectively enrolled in this study. Most patients underwent emergency surgery for Typhoid intestinal perforation (n=80) Tubercular intestinal perforation (n=2), obstruction due to tuberculosis (n=3), or malignancy (n=2), while others had elective surgery for tubercular stricture (n=2) or malignancy (n=11) leading to stoma creation. Patients with malignancy did not receive neoadjuvant treatment.

Patient variables, lab parameters, and significance of their association with POI are shown in Table 1. Alcohol addiction and coexisting comorbidities such as diabetes and tuberculosis were associated with POI. Post-operative nausea and vomiting (PONV), hospital stay, and mortality were significantly higher in the POI group. A total of 7 patients developed POI; PONV was seen in 6 out of 7 patients; and 3 out of 7 patients died. Laboratory parameters and significance of their association with POI are shown in Table 2. Most variables had a significant association with POI; except the platelet count.

On regression analysis, among demographic factors, only body mass index (BMI) (higher odds for BMI ≤18.5) was found to be significantly associated with the occurrence of POI after DI closure (Table 3). Regression analysis showed a significant association between all preoperative lab parameters, the age of the patient, and the occurrence of POI (Table 4). Next, the ROC analysis was conducted to determine the optimal cut-off points for the significance of the variables found to have a significant impact on POI in the univariate analysis (Table 5). Scores were assigned to each factor, and weights were given according to their sensitivities. A prediction model was constructed by performing multivariate analysis with various combinations of the aforementioned factors plus platelet count, resulting in a minimum score of 2 and a maximum score of 12 (Table 6). The ROC analysis on the final scoring system revealed that the highest predictive value of the scoring system was at a cut-off of 7.5. As the scores were in non-decimal values, a cut-off

Table 2. Laboratory parameters and significance of their association with POI

Lab parameter	Ileus group (mean values)	Non ileus group (mean values)	Significance (p-value)
Hb	9.71±0.76	11.32±1.44	0.0044
TLC	14028.57±3176.85	8478.92 ±4351.35	0.0013
Platelets	2.45±0.95	2.77±0.99	0.4104
Albumin (g/dL)	2.62±0.50	3.09±0.25	<0.0001
Creatinine (g/dL)	1.54±0.72	1.07±0.41	0.0070
Sodium (MEq)	142±8.42	135.78±4.98	0.0032
Potassium (MEq)	2.78±0.52	3.57±0.81	0.0128

POI: Postoperative ileus, Hb: Hemoglobin

Table 3. Significance of demographic factors, after regression analysis, with occurrence of POI

Factors		Odds ratio	p-value
Demography	Rural	1 (reference)	0.299
	Urban	0.41	
Sex	Male	1 (reference)	0.175
	Female	0.34	
Addiction of alcohol	No	1 (reference)	0.111
	Yes	3.96	
BMI	≤18.5	1 (reference)	0.042
	>18.5	0.17	
Time before stoma closure	≤3 months	1 (reference)	0.634
	>3 months	1.51	

POI: Postoperative ileus, BMI: Body mass index

Table 4. Significance of preoperative lab parameters and age, after regression analysis, with occurrence of POI						
Factors	**Beta coefficient**	**Standard error**	**Z**	**p-value**	**95% CI**	
					Lower	**Upper**
Age	-0.004	0.002	-2.01	0.047	-0.007	0.000
Hb	-0.039	0.016	-2.44	0.016	-0.071	-0.007
TLC	0.000	0.000	2.9	0.005	0.000	0.000
Platelets	0.053	0.022		0.021	0.008	0.097
Albumin	-0.337	0.079	-4.28	<0.0001	-0.493	-0.181
Creatinine	0.153	0.055	2.76	0.007	0.043	0.262
Sodium	0.014	0.005	3.01	0.003	0.005	0.023
Potassium	-0.077	0.031	-2.52	0.013	-0.138	-0.016

POI: Postoperative ileus, Hb: Hemoglobin, CI: Confidence interval

Table 5. Empirical cut-point and sensitivity of significant factors for POI (from univariate analysis) after receiver operating curve analysis				
Factors	**Empirical cut-point**	**Sensitivity**	**Specificity**	**AUC**
Age	19	86	14	50
BMI	20.45	29	58	43
Hb	9.9	86	10	48
TLC		100	86	93
Albumin	3.25	29	75	52
Creatinine	0.95	100	46	73
Sodium	142.5	86	85	85
Potassium	3.15	57	33	45

POI: Postoperative ileus, Hb: Hemoglobin, AUC: Area under the curve, BMI: Body mass index

Table 6. Cut-off of various parameters used in score evaluation and allotting scores based on their weightage in scoring system for the prediction model (minimum score =2 and maximum score =12)			
Parameters	**Lower cut-off**	**Upper cut-off**	**Scores**
Age	≤19	>19	1 & 2
BMI	<18.5	≥18.5	1 & 2
Alcohol addiction	Yes	No	1 & 0
Comorbidity	Yes	No	1 & 0
Hb	≤9.9	>9.9	0 & 1
Platelets	≤2.1	>2.1	0 & 1
Creatinine	≤0.95	>0.95	0 & 1
S. albumin	≤3.25	>3.25	0 & 1
Sodium	≤142.5	>142.5	0 & 1
Potassium	≤3.15	>3.15	0 & 1

BMI: Body mass index, Hb: Hemoglobin

was set at score 8 with the sensitivity of 85.71%, the specificity of 73.12%, and the AUC was 0.8241 with SE of 0.1123. This means that the above factors contributed 82% towards POI occurrence (Figure 1).

When comparing the overall score of POI and non-POI groups, the mean score was significantly higher (8.29±1.70 vs. 6.28±1.40; t=3.23; p=0.002) in patients with POI. Sixteen patients had a score of >8; however, only 6 patients actually developed POI, 1 patient with POI had a score lower than 8. Out of 7 patients with POI, 6 (85.7%) had scores higher than 8. The sensitivity of the model in predicting POI was 85.71%; the specificity was 89.25% with an accuracy of 89%.

We validated prospectively this predictive model in the next 50 consecutive patients undergoing DI closure. A total of 7 patients had a score >8, of whom 4 actually developed POI. One patient with POI had a score less than 8; sensitivity of the model was 80% and specificity was 93.3% (Figure 2).

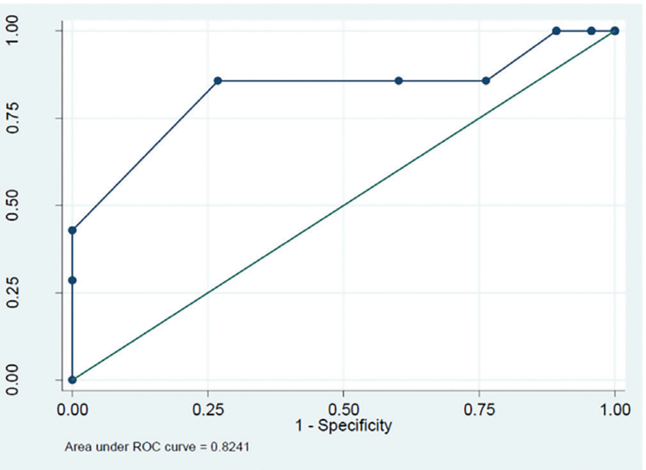

Figure 1. ROC of the predictive model.

ROC: Receiver operating characteristic

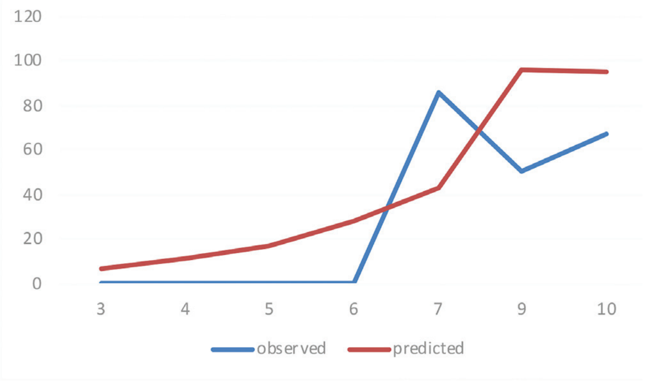

Figure 2. Comparison observed and predicted POI in the validation cohort.

POI: Postoperative ileus

DISCUSSION

POI is a common, challenging complication following ileostomy closure, which can delay patient recovery, increase hospital stay, and healthcare costs significantly. We constructed and internally validated a predictive model to assess POI risk in patients undergoing ileostomy closure. Our model, using logistic regression, identified age, BMI, addiction to alcohol, presence of comorbidities, anemia, thrombocytopenia, renal dysfunction, hypoproteinemia, hypernatremia, and hypokalemia: As key factors associated with POI. The model showed good accuracy, as demonstrated by an AUC of 0.8241 in the derivation cohort and robust sensitivity (85.71%) and specificity (73.12%) at a cut-off score of 8. Furthermore, internal validation in an independent cohort confirmed high predictive value (80% sensitivity, 93.3% specificity), suggesting that our tool could be reliably used to identify patients at heightened risk of POI.

DI is a prophylactic surgical step, that is added when there is a high risk of leakage after surgery for a distal ileal or colorectal pathology; hence prevention of leakage remains the focus of index surgery. However, the morbidity and mortality associated with the later closure of the DI is significant. POI merits attention not only because of its incidence (4-20%) but also because it has its own set of complications such as vomiting and abdominal distention, respiratory difficulties, delay in starting enteral feeds, risk of anastomotic disruption, and even death. POI remains poorly defined and needs an international consensus regarding definition, diagnosis, and treatment (15,16). Its prediction is of special interest because early identification and timely modification of associated factors may prevent its development. High-risk patients might benefit from extended and intensive observations in the hospital and could be offered early interventions (conservative or surgical), thereby potentially changing their outcomes (17). Incidence of POI was 7%, and 10%, respectively, in our derivation cohort and validation cohort.

Many associated risk factors, such as, older patients, high BMI, a >3-month interval for closure, hypertension, coexisting chronic obstructive pulmonary disease, tobacco addiction, and chemotherapy and radiotherapy that were found important in studies from developed countries, were not found significant in our study (8,11,17-19). Time interval for stoma closure was included in the univariate analysis, but it did not emerge as a statistically significant predictor of postoperative ileus. It could be because of the younger study population. Our patients were younger because DI was done most commonly for typhoid enteric perforations and tubercular obstruction or perforations. And even in this cohort, younger patients had a higher incidence of POI. Similarly, we had more male patients, but the incidence of POI was higher (p= not significant) in females. Alcohol addiction was found to be a significant risk factor while tobacco addiction was not found to be one. The relationship between individuals with alcohol addiction and the occurrence of POI could not be found in any previous studies. Low BMI (<18.5) was a significant (p=0.0175) risk factor and can be considered a marker of nutritional status for our patients at the preoperative stage. In the majority (87%) of our cohort, DI was done for benign lesions; none of the remaining patients with malignant indications developed POI in spite of adjuvant chemotherapy and radiotherapy. In our cohort, more (9.4% vs. 4.25%, p= not significant) patients operated for an obstructive pathology developed POI than those operated for perforations. This may be of importance in view of our disease demography, and the exact causal relation is worth future study. Diabetes mellitus and tuberculosis were the two comorbidities associated with POI in our patients. Hypoproteinemia and Hypokalemia were common risk factors, as observed in previous studies (20,21). Patients with a hospital stay of more than 10 days at index surgery were found to have a higher incidence of POI, which may be due to surgical complications, e.g., leak, pelvic sepsis, etc., or medical conditions, e.g., pneumonia, sepsis, cardiac problems. Any intraperitoneal inflammation could lead to an increased likelihood of adhesions later (22,23). Duration between DI and its reversal has been known to affect incidence according to some, but not all, studies (8,24-26). However, it did not reach the significance level, unlike in our study.

Most of these differences can be explained by having a different patient cohort, and, in some cases, by having a smaller number of patients, which prevent the statistical difference from reaching a significant level.

An earlier prediction model developed in Canada included five variables: Increasing age, interval between ileostomy creation and closure, duration of surgery for ileostomy closure, ASA fitness grade, and underlying pathology/treatment (27). Again, the inherent differences between different patient cohorts substantiate the need for developing specific prediction tools for LMICs.

Study Limitations

Our study has some limitations: Factors like use of open vs. minimally invasive surgery, hand-sewn vs. stapler anastomosis, and a prophylactic drain could not be assessed because open surgery for index and stoma closure, hand-sewn anastomosis and a prophylactic drain were used in all our patients. Other missed factors included effects of efferent loop stimulation, epidural anesthesia, operation time, blood loss, post-operative opioid use, and probiotic stimulation. These limitations apart, implementing this predictive model in clinical settings could provide multiple benefits. First, it could facilitate preoperative counseling by giving clinicians a quantitative means to inform patients about their individual risk of POI. This risk-based approach can enhance shared decision-making and set realistic expectations about postoperative recovery. Second, high-risk patients could be triaged for preventive strategies, such as enhanced perioperative hydration, earlier initiation of gut motility agents, or other supportive measures aimed at mitigating POI risk. Moreover, resource allocation could be improved by focusing monitoring and resources on patients at greatest risk of prolonged hospital stays due to POI. This targeted approach could improve efficiency and reduce costs, aligning with modern healthcare objectives that emphasize resource optimization and cost-effectiveness (28,29).

While our model performed well in an internal validation cohort (Figure 2), external validation in larger and more diverse populations is essential to establish its generalizability across different healthcare settings. Future research aimed at external validation in varied clinical and geographical contexts is essential to strengthen the model's applicability and utility in broader surgical practice. All patients underwent open surgery with hand-sewn anastomosis. While this ensured consistency, it also limited applicability of the model in settings using different surgical techniques (e.g., minimally invasive or stapled closure). Moreover, the majority of patients had benign indications for ileostomy. This raises questions about whether the model would be applicable in malignant cases, especially those undergoing adjuvant therapies. This necessitates validation in these clinical contexts, including international cohorts. Further refinement may improve the predictive power of the scoring system. Future studies might also assess whether incorporating additional perioperative parameters—such as intraoperative fluid balance or early postoperative markers—could further enhance model performance. Moreover, prospective trials are needed to evaluate whether implementing this predictive tool and related interventions actually translates to reduced incidence of POI and improved clinical outcomes.

CONCLUSION

We have developed and internally validated a practical, predictive model for POI after ileostomy closure. By enabling early identification of high-risk patients, this model holds promise to improve preoperative planning, enhance patient counseling, and guide targeted interventions. Despite some limitations in generalizability and methodology, it provides a useful model for clinical practice, especially in LMIC settings.

Ethics

Ethics Committee Approval: It was approved by the Institutional Ethics Committee of Netaji Subhash Chandra Bose Medical College Jabalpur (M.P.) (no: IEC/2019/9906, date: 09.12.2019).

Informed Consent: Patients presenting for DI reversal, irrespective of the indication for creation, were prospectively enrolled in this study.

Footnotes

Author Contributions

Surgical and Medical Practices - A.V., D.K., A.K.; Concept - R.K., D.K., A.V.; Design - R.K., D.S., P.A.; Data Collection or Processing - A.V., A.K., D.K.; Analysis or Interpretation - A.V., A.K., D.K.; Literature Search - R.K., D.S., A.K.; Writing - A.B., D.S.

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