Original Article

Can Patients with Crohn's Disease Benefit from Two-stage Operation?

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Key Words
Crohn's disease;
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Purpose. Almost half of patients with Crohn's disease (CD) receive re-operation 20 years after their initial surgery. Anastomotic recurrence is an important issue. Numerous methods and risk factors for adult CD populations have been established. Although stage operation is an option for patients with CD during emergencies, the risk factors and techniques for preventing postoperative recurrence remain unknown.
Methods. Patients with CD who received operation in our surgery department from January 2006 to December 2020 were retrospectively enrolled. A total of 31 patients were included, among whom eight received two-stage operation. The procedures included the resection of the lesion with diverting enterostomy/colostomy followed by the closure of the enterostomy/colostomy after 3-6 months. Thirty-one patients received one-stage operation with primary anastomosis. Their medical history was reviewed, and their preoperative, operative, and postoperative parameters were recorded and analyzed.
Results. One patient in the two-stage operation group experienced surgical recurrence and five cases in the one-stage operation group experienced surgical recurrence after a mean follow-up of 97 months. Chi-square test showed that postoperative recurrence had no statistically significant correlation with two-stage and one-stage surgery ($p = 0.56$). However, wound infection and ileus and high-out stoma events were higher in the two-stage operation group than in the one-stage group.
Conclusions. In patients with CD who received operation, either one-stage or two-stage operation had no impact on surgical recurrence.

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Given that new medications have emerged recently, medical treatments have become the major way to control Crohn's disease (CD). However, surgical treatments retain their role in treating refractory disease or complications. A meta-analysis showed CD patients were at risk of surgery for CD complications up to 57% within 10 years after diagnosis.[1] At the time that patients with CD require operation, they need surgery not only to address CD complications but malnutrition or immunocompromised status due to the CD medications that they received. Definite operation, i.e., intestinal or colon resection with anastomosis, may be unsuitable during emergent situations in sepsis, perforation, obstruction, and malnutrition cases. Diverting ileostomy or colostomy is required in patients with such conditions to address anastomotic leakage or further complications, and bowel continuity is then restored after diversion to improve the patient's nutritional status. Such two-stage operation is commonly done in surgeries on patients with CD.

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However, literature comparing the risk of reoperation and complications between two-stage operation and one-stage operation in patients with CD is limited.[5-7]

Postoperative recurrence remains an issue after surgical resection. Reoperation rates for recurrence, known as surgical recurrence, have been reported to be 10%-30% at 5 years, 20%-40% at 10 years, and 40%-60% at 20 years postoperatively.[2-4] There are several factors that can impact the rate of anastomosis recurrence in CD patients. For example, smoking can increase the recurrence rate by two-fold in CD patients.[22] Additionally, penetrating disease in CD patients may result in a shorter re-operation interval compared to non-penetrating disease (2 years vs. 9.9 years, $p < 0.05$).[23] The usage of immunomodulators during the post-operative period has been found to be effective in preventing endoscopic recurrence.[24] In the 1990s, Rutgeerts et al.[12] and Nugent et al.[13] hypothesized that fecal stream bypass could rest the bowel and decrease inflammation, and their research demonstrated that fecal diversion patients had a lower recurrence rate. However, the surgical outcomes of stage operation in CD patients, which may have a fecal diversion effect for the operative lesion, have been rarely discussed.

Postoperative complications, including long-term anastomosis recurrence, have been issues in patients with CD owing to the usage of immunosuppressants and steroids.[8,9] Postoperative complication rates have increased given that some patients undergo emergent operations under circumstances, as bowel obstruction, infection, and perforations. In our center, we perform either two- or one-stage operations on such patients. In two-stage operation, bowel resection with ostomy creation is performed first. The ostomy is closed 3-6 months later or after achieving clinical stability under medication. Here, we present these cases and compare their clinical results. We also analyze their postoperative complications and risk factors.

Materials and Methods

Patients

Our subjects were patients with CD who underwent operation at Taichung Veterans General Hospital from January 2006 to September 2020. Their medical records were reviewed, and their characteristics, surgical parameters, complications, and clinical outcomes were retrospectively recorded. Surgical indications, such as intestinal obstruction, intestinal perforation, and enteral fistulas, were documented. The patients' diseases were further described on the basis of the Paris Classification as follows: Location: (L1) distal ileum with/without cecal disease, (L2) colonic, (L3) ileocolonic, and (L4) upper disease. Disease behavior: (B1) non-stricturing, (B2) stricturing, (B3) penetrating, and (B2B3) stricturing and penetrating disease.[10] The inclusion criteria for eligible patients were as follows: (1) patients with CD who received one-stage operation with bowel resection for the first time at our hospital or (2) patients with CD who underwent two-stage operation and received ostomy creation and ostomy closure at our hospital. The exclusion criteria were as follows: (1) missing or incomplete medical records and (2) follow-up at our outpatient clinic less than 12 months after operation.

Operation

The operations were classified into two groups: one- and two-stage operation. One-stage operation was defined as the resection of the affected colon or small intestines with direct anastomosis at the same time regardless of technique type. Two-stage operation was defined as the resection of the lesion with ostomy creation initially followed by ostomy closure after 3-6 months. The diverting ostomy operation included loop ileostomy, Hartman operation, and double-barrel enterostomy. The anastomosis technique included stapled or hand-sewn anastomosis. The anastomosis fashion included side-to-side anastomosis, end-to-end anastomosis, or side-to-end anastomosis. The decision to perform a one-stage or two-stage operation was based on factors such as the patient's nutrition status, hemodynamic condition, and whether the operation was emergent or not.

Outcomes

The primary outcome of this study was surgical

recurrence, which was defined as reoperation with resection for the recurrent disease at the previous anastomotic site with pathological, clinical, or radiologic evidence. Endoscopic recurrence was defined on the basis of endoscopic findings and the related symptoms of CD. Short-term complications were listed and stratified on the basis of Clavien Dindo classification in accordance with medical records. SSI was defined as positive culture results of surgical wounds and wounds requiring wet dressing or surgical debridement. In this work, steroid usage was defined as taking more than 10 mg of prednisolone for 4 weeks or prior steroid usage that was stopped within 2 weeks before surgery.

Statistics

Statistical analysis was performed by using the chi-square test to compare categorical variables. Quantitative data were presented as mean ± standard deviation and compared by using unpaired *t*-test. The range was given when appropriate. Possible risk factors analysis for surgical recurrence were analysis by univariate analysis. The threshold of significance in all analyses was $p < 0.05$. All analyses were performed by using SPSS 22.0 (IBM, USA).

Results

Demographic data

From January 2006 to September 2020, 31 patients with CD received surgery in our hospital. Eight patients underwent two-stage operation, and 23 underwent one-stage operation. Table 1 lists the sex, age at operation, body mass index (BMI), surgical lesion type, lesion site, and anastomosis technique. No sig-

Table 1. Patient characteristic

	Two stage	One stage	*p* value	Mean difference (confidence interval)
Number of patients	8	23		
Male/female ratio	62.5% (5/8)	73.9% (17/23)		
Mean age at operation	30.88 ± 6.22	20 ± 2.85	0.531	-3.21 (-15.56 to 9.14)
BMI	16.71 ± 2.92	20.32 ± 4.60	0.05	-3.62 (-7.24 to 0)
Lesion type [a]			0.14	
B1	0	3		
B2	1	10		
B3	6	7		
B2B3	1	3		
Anastomosis fashion			0.34	
Side to side	5	11		
End to end	3	5		
Side to end	0	2		
Total colectomy	0	5		
Lesion site [a]			0.059	
L1	0	9		
L2	4	4		
L3	4	10		
Anastomosis technique			0.27	
Staple	6	11		
Hand	2	7		
Others	0	5		
Recurrence				
Surgical recurrence	1	5	**0.39**	
Endoscopic anastomotic recurrence	5	6	**0.16**	
Steroid usage	2	3	0.42	

[a] Paris classification.

nificant difference existed between the two groups. The two-stage group included five male patients (62.5%), and the one-stage group had 17 male patients (73.9%). The mean ages of the two- and one-stage groups were 30.9 and 20 years, respectively, the mean difference between the two groups was -3.21 years, and the confidence interval for the mean difference was -15.56 to 9.14. The mean BMIs of the two- and one-stage groups were 16.7 and 20.3, respectively. Age did not significantly differ between the two group. However, BMI was significantly lower in the two-stage group than in the one-stage group ($p = 0.05$).

In the two-stage group, one patient had stricturing disease (B2), six had penetrating disease (B3), and one patient had stricturing and penetrating diseases (B2B3). In accordance with the Paris Classification of IBD, of the patients, none had ileum ± cecum disease (L1), four had ileocolonic (L3) involvement, and four had colonic (L2) involvement. In terms of anastomotic technique, five received stapled side-to-side anastomosis and three received hand-sewn end-to-end anastomosis.

Among the patients in the one-stage group, three had non-structuring non-penetrating disease (B1), ten had a stricturing disease (B2), seven had a penetrating disease (B3), and three had stricturing and penetrating diseases (B2B3). Among these 23 patients, nine had ileal (L1) involvement, four had colonic involvement (L2), and ten had ileocolonic (L3) involvement. In terms of the anastomotic technique, of the patients, eleven received stapled side-to-side anastomosis, five received hand-sewn end-to-end anastomosis, two received hand-sewn end-to-side anastomosis, and five received total colectomy.

The comparison of lesions revealed no significant difference between the two groups in terms of lesion type ($p = 0.14$) or CD lesion site ($p = 0.059$).

Surgical recurrence

The number of patients with surgical recurrence and endoscopic recurrence are listed in Table 1. All patients underwent follow-up colonoscopy or upper gastrointestinal endoscopy after operation. The mean follow-up time was 83 in the two-stage group and 102 months in the one-stage group. In the two-stage operation group, only one patient experienced surgical recurrence. The patient received right hemicolectomy with double-barrel enterostomy followed by enterostomy closure 3 months later. The patient experienced surgical recurrence 104 months after the initial operation and received a subtotal colectomy. Of the patients in the one-stage group, ten experienced endoscopic recurrence and five had surgical recurrence. The mean surgical recurrent time was 105 months in the two-stage group and 74 months in the one-stage group. In terms of endoscopic recurrent events, endoscopic recurrence was observed in six patients in the two-stage group and in nine patients in the one-stage group. No significant difference in terms of surgical or endoscopic recurrence was found between the two-stage and one-stage operation groups.

The risk factors for surgical recurrence are listed in Table 2. Intestinal perforation (B3), previous abdominal operation, two- or one-stage operation, postoperation TNF-alpha, and disease location (L1/L2/L3) were unrelated to recurrence. Among six anastomotic recurrent cases, four received end-to-end anastomosis and the other two received side-to-side anastomosis. Among 25 patients without surgical recurrence, four received end-to-end anastomosis, two received end-to-side anastomosis, and fourteen received side-to-side anastomosis. These results showed increased risk for surgical recurrence only in end-to-end anastomosis relative to end-to-side and side-to-side anastomoses (OR 10.05, $p = 0.01$).

Short-term complications

The short-term complications are listed in Table 3 and grouped in accordance with Clavien-Dindo classification. Most complications were grades I and II. Both groups had one grade III cholecystitis event postoperatively. No grade IV event or life-threatening complications were observed in both groups. Chi-square analysis revealed that the two-stage operation group had more wound infections and high output stomas in the first stage than the one-stage operation group (62% vs. 17%, $p = 0.015$. 50% vs. 0%, $p = 0.0002$). The two-stage operation group had more ileus episodes in

Table 2. Risk factors for surgical recurrence

	Anastomotic recurrence	No anastomotic recurrence	OR (odds ratio)	95 % confidence interval	*p* value
Cases	6	20			
Perforation	2	13	0.27	0.039-1.855	0.18
Previous abd op [a]	2	7	0.93	0.134-6.398	0.94
Post operative anti TNFa	0	5	0.21	0.010-4.5162	0.32
Location [b]					
L1	3	6	1		
L2	0	6	0.14	0.006-3.355	0.22
L3	3	8	0.75	0.110-5.109	0.76
Two-stage	1	7	0.37	0.036-3.838	0.40
End to end	4	4	8.00**	1.061-60.326	0.04**

[a] Previous abdominal operation. [b] Paris classification.
** $p < 0.05$.

Table 3. Risk factors for short term complications (Clavien Dindo classification)

Post op complications	Group 1 (N = 23) [c]	Group 2 [d] (N = 8)	Group 2 [d] (N = 8)	*p* value [a]	*p* value [b]
		First stage	Second stage		
Grade I	12 (52%)	6 (75%)	7 (87%)		
Wound infection	4 (17%)	5 (62%)	2 (25%)	**0.015**	0.64
Ileus	1 (4%)	1 (13%)	3 (38%)	0.41	**0.015**
Nausea vomiting	3 (13%)	0 (0%)	1 (13%)	0.28	0.96
Edema	1 (4%)	0 (0%)	0 (0%)	0.54	0.54
Diarrhea	3 (13%)	0 (0%)	1 (13%)	0.28	0.97
Grade II	7 (30%)	8 (100%)	0 (0%)		
Intestinal obstruction	1 (4%)	0 (0%)	0 (0%)	0.54	0.54
High output stoma	0 (0%)	4 (50%)	0 (0%)	**0.0002**	
UTI	1 (4%)	0 (0%)	0 (0%)	0.54	0.54
Anemia	2 (8%)	1 (13%)	0 (0%)	0.78	0.37
Bacteremia	1 (4%)	0 (0%)	0 (0%)	0.54	0.54
Intra-abdmimal infection	2 (8%)	3 (38%)	0 (0%)	0.06	0.38
Grade III	1 (4%)	1 (13%)	0 (0%)		
Cholecystitis	1 (4%)	1 (13%)	0 (0%)	0.54	0.54
Grade IV	0 (0%)	0 (0%)	0 (0%)		
Infectious shock	0 (0%)	0 (0%)	0 (0%)		

[a] *p* vavlue comparing gourp 1 and fisrt stage of group two. [b] *p* vavlue comparing gourp 1 and second stage of group two.
[c] Group 1 means one stage operation. [d] Group 2 means two stage operation.

the second stage than the one-stage group (38% vs. 4%, $p = 0.015$). Although more intra-abdominal infection events were observed in the first stage of the two-stage operation than in the one-stage operation (38% vs. 8%, $p = 0.06$), this difference had a statistically insignificant *p* value.

Discussion

Nearly 25% of patients with CD are diagnosed by the first two decades of their life.[7] Surgical intervention methods for CD vary, and the comparison of recurrence following first operation with that in two- and one-stage operation has not been extensively discussed. In this study, we investigated 31 cases to compare short-term complications and surgical recurrence after two- or one-stage operation. No difference in surgical site, surgical indication, or anastomosis type was found between the two- and one-stage operation groups. However, compared with the one-stage group, the two-stage group had a slightly significantly lower

BMI, which could be attributed to this group's poor nutritional status. Such status affected the surgical decision of creating a diversion ostomy instead of anastomosis alone.

We observed only one instance of surgical recurrence in the two-stage group. The overall recurrence rate was 19% during a mean follow-up period of 97 months. A previous systemic review showed a recurrence rate of 24.2% (95% CI = 22.3%-26.4%) in patients with CD within 5 years of reoperation.[11] Our data revealed a slightly lower risk of surgical recurrence, and no correlation was found between staged operation and surgical recurrence ($p = 0.56$). In 1991,[12] Rutgeerts et al. conducted a study to confirm the importance of fecal diversion for the pathogenesis of recurrence. Five patients with CD had ileal resection with diverting terminal ileostomy. Although no recurrence over the neoterminal ileum in the first 6 months were found endoscopically and microscopically, all patients experienced recurrence after ileostomy reversal. Similarly, Nugent et al.[13] demonstrated that 66% of patients without ileostomy after anastomosis experienced recurrence compared with 3% of patients with ileostomy. The present study revealed different opinions and found that initial stool diversion was unrelated to a low recurrence rate.

The literature states that several factors, such as disease phenotype and affected sites, affect postoperative recurrences. Penetrating disease and perianal involvement are positively correlated with postoperative recurrence. An observational study showed that ileal disease is a significant risk for second ileocolonic resections (OR = 2.4; 95% CI = 1.02-5.78; $p = 0.05$).[14] By contrast, other studies demonstrated no correlation between location and postoperative recurrence.[15,16] In the current study, we found no correlations between anastomotic recurrence and disease location ($p = 0.21$).

A retrospective study by Avidan et al. concluded that penetrating disease is a significant risk factor for surgical recurrence ($p = 0.024$).[15] One meta-analysis discovered that perforating disease is associated with postoperative recurrence (HR = 1.50; 95% CI = 1.16-1.93, $p = 0.002$).[17] In this observational study, we found no correlation between penetrating disease (Paris Classification B3) and surgical recurrence. Our observation differed from that in the literature possibly because of the small number of our cases and improvements in postoperative medical control.

We found a significant difference in postoperative recurrence between the end-to-end technique or other anastomosis techniques (i.e., side-to-side and side-to-end) ($p = 0.01$). Researchers have debated on the superior anastomosis technique for reducing postoperative recurrence and complications. A randomized controlled trial[18] reported that endoscopic recurrence was 42.5% in the end-to-end group and 37.9% in the side-to-side group ($p = 0.55$) after a mean follow-up period of 12 months. Conversely, a meta-analysis including eight studies concluded that side-to-side anastomosis was superior in terms of overall postoperative complications (OR = 0.45; 95% CI = 0.32-0.93) and surgical recurrence (OR = 0.18; 95% CI = 0.07-0.45).[19] Another anastomosis technique emphasizing the antimesenteric hand-sewn method, namely, Kono-S anastomosis, has a 10-year surgical recurrence-free survival rate of 98.6%. Although our present study included two cases of side-to-end anastomosis instead of purely comparing end-to-end and side-to-side anastomoses, we concluded that end-to-end anastomosis had significantly increased recurrence than other methods. Here, we also demonstrated other possible anastomosis techniques aside from side-to-side and end-to-end anastomosis, among which two of the side-to-end anastomosis methods had no recurrent episode during follow-up.

In terms of short-term complications, wound infection and ileus rates and high-output stoma were significantly higher in the two-stage operation group than in the one-stage operation group. A retrospective study showed that patients with CD had wound infection rates of 5.4%-14% after operation and that high-output stoma caused electrolyte imbalance in 10.9% of patients.[20] Other studies showed that in patients with penetrating CD after ostomy surgery, 19% experienced dehydration caused by high-output stoma.[21] Our study found higher wound infection rates (17%-62%) and high output stoma rates (50%) than other works likely due to the relatively small number of cases studied. In the two-stage group, the increase in ostomy output and ileus and wound infection rates

was correlated with low BMI, in which malnutrition is known to affect SSI rates. Other factors, including intestinal perforation (Paris Classification B3), previous abdominal operation, steroid usage, and laparoscopic procedures, were unrelated to short-term complications. No postoperative mortality was found in the current series. However, given that the mean follow-up period was 97 months, a longer follow-up is needed. The other limitation of the current study is its small number of patients.

Limitations

As the incidence of CD is relatively low in the Asian region, our study primarily emphasizes the management and outcomes of initial surgeries. However, it is important to acknowledge the limitations of our research, namely the small number of patients included. Additionally, our study was conducted retrospectively, which introduces potential selection bias when comparing one-stage operations with two-stage operations. The patient grouping was based on clinical judgment or surgeon preference, further complicating the analysis. To better understand the relationship between stage of operation and surgical recurrence in CD patients, we recognize the need for a larger patient cohort and the implementation of propensity score analysis.

Conclusions

Two- and one-stage operations could be safe and effective treatment choices for patients with CD requiring surgery. Neither recurrence nor complication could be altered by surgical strategy. The end-to-end anastomosis technique was related to recurrence. Other factors were not significant for recurrence or short-term complications. Further studies on groups of patients with CD are required.

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Conflict of Interest Statement

The authors declare no conflict of interest in this study.

Role of the Funding Source

The authors declare that the funding source has no role in this study.

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原　著

克隆氏症患者是否能從二階段手術獲益？

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目的　幾乎一半的克隆氏症患者在初次手術後 20 年接受再次手術。吻合復發一直是克隆氏症患者接受吻合術後重要的議題。許多文獻討探討克隆氏症患者復發的風險評估和方法。對於緊急開刀的克隆氏症患者，階段性手術是常見的術式。然而階段性手術是否影響吻合處的復發仍是未知，本研究在於分析階段性手術、吻合方式以及風險因子對於吻合處復發的關聯性。

方法　我們回顧性納入 2006 年 1 月至 2020 年 12 月在台中榮民總醫院接受手術的克隆氏症患者，共 31 例，其中包含，8 例接受二階段手術，23 例接受一階段手術。二階段手術的定義為切除病灶並且行腸造口術，3 至 6 個月接受腸造口關閉手術。資料來源根據病歷紀載，記錄和分析術前、術中和術後參數。

結果　平均追蹤 97 個月後，二階段手術組有 1 例因復發行手術，一階段手術手術中有 5 例。卡方 (χ^2) 檢驗顯示一階段和二階段手術兩者術後復發無統計學相關性 ($p = 0.56$)。

結論　克隆氏症患者接受手術後，一階段或是二階段手術對於術後併發症以及吻合復發率皆無顯著性影響。

關鍵詞　克隆氏症、一階段手術、二階段手術、吻合處復發。