Original Article

Anastomotic Leakage following 4,357 Colorectal Cancer Surgery: Incidence, Presentation, Pathogens, Treatment and Outcome

Lohsiriwat V, MD, PhD[1], Assawasirisin C, MD[1]

[1] Colorectal Surgery Unit, Department of Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand

Objective: This study aimed to determine the incidence, presentation, pathogens, treatment and outcome of patients with anastomotic leakage (AL) after colorectal cancer surgery.

Materials and Methods: The authors retrospectively reviewed the medical records of patients with clinical AL after colorectal cancer surgery during 2004 to 2015 at the Faculty of Medicine Siriraj Hospital, Mahidol University, Thailand.

Results: AL occurred in 84 of 4,357 patients (1.9%): right hemicolectomy (1.4%), left hemicolectomy (1.1%), sigmoidectomy (2.1%), and other sphincter-saving operations (2.4%). AL was commonly diagnosed on postoperative day 3 to 7 with peak on day 4. Eleven cases (13%) were diagnosed after patients were discharged. The most common manifestations of AL were postoperative ileus (n = 67, 80%), fever (n = 64, 76%), and oliguria (n = 62, 74%). Localized peritonitis or generalized peritonitis presented in 24 cases (29%) and 11 cases (13%), respectively. Eleven cases (13%) had septic shock. Some 67 AL cases (80%) required surgery and majority of patients requiring surgery had stoma formation. Nine patients (11%) died. Sixty-three cases (75%) suffered from other complications after treating AL-mostly wound infection and residual intraabdominal collection. Average total length of hospital stay was 30 days. Regarding bacteriology, *Escherichia spp.* was the most common pathogens followed by mixed organisms and *Enterococcus spp.* Extended-spectrum beta-lactamase (ESBL) producing organisms were found in 31%.

Conclusion: This study demonstrated a relative low incidence of AL after colorectal cancer surgery but it was associated with significant morbidity and mortality. Most cases required surgical treatment and stoma formation. Antimicrobial-resistant bacteria were identified in about one-third of AL cases.

Keywords: Anastomotic leakage, Incidence, Presentation, Management, Colon, Rectum, Surgery, Cancer, Thailand, Extended-spectrum beta-lactamase (ESBL)

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Colorectal cancer is the third leading cancer death in Thailand[1]. Surgical removal of tumor and node-bearing area remains a mainstay treatment of colorectal cancer-aiming to cure the disease and improve patient's quality of life. There is evidence suggesting that patients undergoing colorectal resection with bowel anastomosis could have better quality of life and less morbidity than individuals undergoing bowel resection without anastomosis i.e. having stoma formation[2]. However, the most serious complication after lower gastrointestinal anastomosis is anastomotic leakage (AL)-in which the reported incidence ranged from 1% to 20%[3,4] depended on the indication for surgery, patient's underlying disease, the location and technique of anastomosis, and surgeon's experience. AL is associated with a high rate of morbidity and mortality. The reported morbidity following AL was at least 20%[5], and mortality ranged 0 to 54.6% (pooled mortality of 8.3%)[3], which were dependent on patients' characteristics and co-morbidities, hemodynamic status and degree of intraperitoneal contamination. Most patients with AL require reoperation and may have a formation of stoma[6].

Although there is a few reports published about AL after lower gastrointestinal anastomosis from Thailand, their details were based on small sample size and quite dated[5,7]. Moreover, no comprehensive data of presentation, pathogens, treatment and outcomes of patients with AL after colorectal surgery were reported from Thailand. The aims of this study were therefore to determine the incidence of AL following colorectal cancer surgery and to evaluate clinical presentation, pathogens, management and outcome of patients with AL from the largest tertiary university hospital in Thailand.

Correspondence to:

Lohsiriwat V.

Department of Surgery, Faculty of Medicine Siriraj Hospital, Mahidol University, 2 Wang Luang Road, Bangkok 10700, Thailand.

Phone: +66-2-4198005, **Fax:** +66-2-4121370

E-mail: bolloon@hotmail.com

Materials and Methods

Patients

After obtaining an ethical approval from the Siriraj Institutional Review Board, the authors retrospectively

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reviewed the medical records of patients with clinical AL after colorectal cancer resection with bowel anastomosis during 2004 to 2015 at the Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand. Patients with AL were identified from the hospital information system. Only clinical or symptomatic AL was included in this study. We defined AL according to the International Study Group of Rectal Cancer-in which AL is a defect of the intestinal wall at the anastomotic site which leads to a connection between intraluminal compartment and extraluminal compartment[8]. Notably, clinical AL was considered to be present if any of the followings was observed: gas or fecal content from the wound or the vagina or a drain, fecal or purulent peritonitis, and an intraabdominal abscess or collection along with an anastomotic defect verified by rectal examination, image study, endoscopy or at laparotomy[5]. Patients were excluded from the study if an operation was in an emergency setting. Local excision and non-segmental bowel resection were also excluded. The present study was approved by the Siriraj Institutational Review Board (066/2557(EC2)).

Outcome measurement and data collection

Incidence, presentation, bacteriology from culture of intraabdominal fluid/abscess/debris, treatment and outcomes of patients with AL after colorectal cancer surgery were determined. The incidence of AL was further classified by 4 major categories as following: (1) right hemicolectomy included right hemicolectomy, extended right hemicolectomy and transverse colectomy, (2) left hemicolectomy included left hemicolectomy and extended left hemicolectomy, (3) sigmoidectomy included sigmoidectomy and subtotal colectomy with ileosigmoid anastomosis, and (4) other sphincter-saving operations included anterior resection, low anterior resection, total abdominal colectomy with ileorectal anastomosis, and total proctocolectomy with ileoanal anastomosis.

Regarding the presentations (symptoms and signs) of AL, fever was defined as body temperature ≥37.8°C. Oliguria was defined as urine output <0.5 mL/kg/hour. Postoperative ileus was defined when at least two of the following 5 criteria on or after postoperative day 4 were presented: nausea or vomiting, abdominal distension, inability to tolerate oral diet over 24 hours, absence of gas or stool passing over 24 hours, and radiological evidence of ileus[9]. Diarrhea was defined as loose stools three or more times a day. Leukocytosis was defined as an elevated while blood cell count greater than 11,000 per mm^3. Patients' characteristics were also collected.

Statistical analysis

Data were prepared and compiled using the Statistical Package for the Social Sciences program version 18.0 for Windows (SPSS Inc, Chicago, IL). Continuous variables were expressed as mean (standard deviation: SD, or range). Categorical data were expressed as number (percentage).

Results

During the study period of 12 years, AL occurred in 84 of 4357 colorectal cancer patients (1.9%): right hemicolectomy (1.4%, n = 16 of 1,163), left hemicolectomy (1.1%, n = 5 of 471), sigmoidectomy (2.1%, n = 18 of 878), and other sphincter-saving operations (2.4%, n = 45 of 1,845) (Figure 1). Patients with AL had an average age of 64.2 years (SD 12.6, range 23 to 90) with average BMI of 22.7 (SD 4.3, range 15.1 to 34.6). AL was commonly diagnosed on postoperative day 3 to 7 with the highest number on postoperative day 4 (Figure 2) and 11 out of 84 AL cases (13%) occurred after patients were discharged.

The most common manifestations of AL were postoperative ileus (n = 67, 80%), fever (n = 64, 76%), and oliguria (n = 62, 74%). Localized peritonitis or generalized peritonitis presented in 24 cases (29%) and 11 cases (13%), respectively on the day of AL diagnosis. Eleven cases (13%) had hemodynamic instability or septic shock. Fifty-four cases

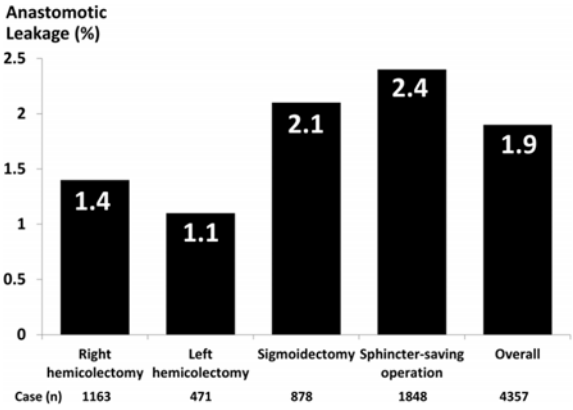

Figure 1. Incidence of 'clinical' anastomotic leakage after colorectal surgery.

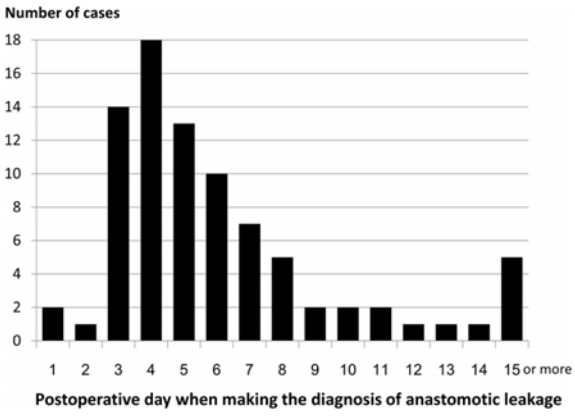

Figure 2. Time from an operation to the diagnosis of anastomotic leakage and number of cases per day.

(64%) underwent CT scan of whole abdomen. Clinical presentations of AL are shown in Table 1.

Of all 84 AL patients, 67 cases (80%) required surgery and 11 cases (13%) had two or more operations for managing AL. The remaining AL cases (n = 17, 20%) needed only board-spectrum intravenous antibiotics with or without percutaneous drainage of intraabdominal collection. Overall, 33 cases (39%) required anastomotic breakdown and 61 cases (73%) had stoma formation at some stages of their AL treatment. Management of AL is shown in Table 2. Forty cases (48%) needed ICU admission. Nine patients (11%) died during hospitalization. Some 63 cases (75%) suffered from other complications after treating AL-mostly wound infection (n = 31, 37%) and residual intraabdominal collection (n = 16, 19%). Complications following the management of anastomotic leakage are shown in Table 3. Average total length of hospital stay in AL cases was 30 days (SD 18, range 7 to 94).

Regarding bacteriology in AL cases, 55 samples of intraperitoneal fluid/pus or tissue were obtained and 51 samples had 'positive' one or more bacterial cultures. *Escherichia spp.* was the most common pathogens identified (n = 22) followed by mixed organisms (n = 17) and *Enterococcus spp.* (n = 14). *Pseudomonas spp.* and *Klebsiella spp*. were found in 9 samples and 6 samples, respectively (Figure 3). Antimicrobial sensitivity was reported in 32 cultures and extended-spectrum beta-lactamase (ESBL) producing organisms were found in 10 out of 32 samples (31%).

Table 1. Clinical presentations of anastomotic leakage in 84 cases. They are presented in order of frequency and one patient may have more than one clinical presentations

Clinical presentation	Number (percentage)
Postoperative ileus	67 (80)
Fever	64 (76)
Oliguria	62 (74)
Leukocytosis	38 (45)
Diarrhea	24 (29)
Localized peritonitis	24 (29)
Generalized peritonitis	11 (13)
Septic shock	11 (13)
Wound discharge with fecal or enteric content	10 (12)
Fecal or enteric content from intraabdominal drain	3 (4)

Discussion

This observational study in a very large university hospital in Thailand demonstrated an overall leakage rate of 1.9% after 4,357 colorectal cancer surgery with gastrointestinal anastomoses. Although the incidence of AL was relatively low, it was associated with a high incidence of morbidity and mortality. Most AL cases required surgical treatment and stoma formation. Average length of hospital stay was 30 days and in-hospital mortality was 11%. Common pathogens identified from intraabdominal collection/abscess were *Enterobacteriaceae spp.* and *Enterococcus spp.* Moreover, one-third of *Enterobacteriaceae spp.* were ESBL-producing organisms.

In this study, AL occurred in 1.9%: right hemicolectomy 1.4%, left hemicolectomy 1.1%, sigmoidectomy and other sphincter-saving operations 2.4%. These incidences of AL were quite in line or relatively lower than those reported in a recent large systematic review of colorectal AL: 1 to 4% for ileocolonic anastomosis (right hemcolectomy), 2 to 3% for colocolic anastomosis (left hemicolectomy or sigmoidectomy) and 5 to 19% for colorectal anastomosis (sphincter-saving operations)[10]. There are several possible explanations for a low incidence of AL after colorectal surgery. First, we identified only AL with significant clinical presentation (i.e. symptomatic)-otherwise radiological AL usually detected more number of AL[11]. Second, several patients had diverting stoma during the index operation for sphincter preservation including those with neoadjuvant chemoradiation or coloanal anastomosis[5]-thus making a reduction in the incidence of AL and its clinical

Table 2. Management of 84 anastomotic leakages

Type of surgery (number)	Management - in order of frequency (number)
Right hemicolectomy (16)	Dismantled anastomosis and double-barreled stoma (5), PCD (5), ATB alone (3), primary repair (2), primary repair with diverting stoma (1)
Left hemicolectomy (5)	Hartmann's procedure (2), abdominal toilet plus diverting stoma (2), primary repair (1)
Sigmoidectomy (18)	Hartmann's procedure (6), ATB alone (5), primary repair (3), primary repair with diverting stoma (2), abdominal toilet plus diverting stoma (1), PCD (1)
Sphincter-saving operation (45)	Hartmann's procedure (20), abdominal toilet plus diverting stoma (16), primary repair with diverting stoma (5), PCD (3), diverting stoma plus PCD (1)

ATB = Antibiotics, PCD = Percutaneous drainage

Table 3. Complications following the management of 84 anastomotic leakages. One patient may have more than one complication

Complication	Number (percentage)
No complication	21 (25)
Wound infection	31 (37)
Intraabdominal collection	16 (19)
Enterocutaneous fistula	7 (8)
Early postoperative small bowel obstruction	4 (5)
Cardiac complication	8 (10)
Pulmonary complication	8 (10)
Renal impairment	5 (6)

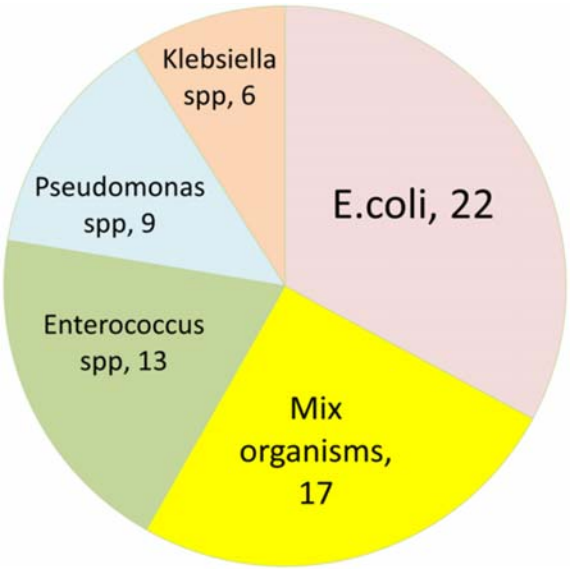

Figure 3. Pathogens identified from intraabdominal collection or infected tissue of some patients with anastomotic leakage.

presentation[12]. Third and more importantly, we always apply a rule-of-thumb for 'safe' gastrointestinal anastomosis which includes good blood supply, tension-free anastomosis, and air-tight anastomosis. For stapled anastomosis, we also appreciate the importance of the interaction between stapling device and local tissue[13] e.g. choosing an appropriate closure height of the stapling device and pre-compression before firing a staple.

In this study, AL was commonly diagnosed on postoperative day 3 to 7 with a peak on postoperative day 4. It is known that phase and time course of gastrointestinal and cutaneous healing is different[14]. In gastrointestinal healing, total amount of collagen (collagen synthesis minus collagen degradation) in the bowel wall was lowest on postoperative day 3-5 causing the highest incidence of AL during this period. However, AL can occur any day after an operation. Of note, in the era of enhanced recovery program in which patients were recovery quicker and discharged earlier-usually on postoperative day 4[15,16], 13% of AL in this series were diagnosed after patients were discharged-thus raising the importance of detailed advice to patients and their family regarding early warning symptoms and signs of AL. We found that postoperative ileus, fever and oliguria were common manifestations suggesting of AL. A high index of suspicion is necessary in patients with these presentations to make an early diagnosis of AL. In addition to clinical manifestations, C-reactive protein is a useful and sensitive biomarker for detecting infectious complication including AL[17].

This study confirms a high incidence of morbidity and mortality in patients with AL. It resulted in 11% in-hospital mortality and 75% complication rate. Since this study included only symptomatic AL representing a sizable defect of the anastomosis site with fecal or purulent intraabdominal infection, most AL cases required surgery and stoma formation. Apart from clinical grounds, CT scan of whole abdomen may indicate various therapeutic approaches to leakage including percutaneous drainage of intraabdominal collection or abscess, or bowel rest with intravenous board-spectrum antibiotics. The average total length of hospital stay in AL cases was about 30 days-which was similar to our previous report with 14 cases of AL after rectal operations in 2008-in which AL cases had 32-day hospitalization and tumor height within 5 cm from the anal verge was a significant risk factor for AL-with an odd ratio of 4[5].

Regarding bacteriology in AL cases, *Enterobacteriaceae spp* (*Escherichia coli* and *Klebsiella spp*) and *Enterococcus spp*. were the most common pathogens identified from intraabdominal collection/abscess. Many AL cases had one or more 'positive' bacterial cultures. Notably, one-third of *Enterobacteriaceae spp*. were ESBL-producing organisms. Accordingly, intravenous board-spectrum antibiotics covering both ESBL-producing *Enterobacteriaceae spp*. and *Enterococcus spp*. should be administrated as an empirical therapy before changing to specific antibiotics when the pathogens are identified with a report of antibiotics susceptibility.

Although this study is the largest report on AL after colorectal surgery from Thailand – to the best of our knowledge, some limitations of this study needed to be addressed. First, this study has the inherent problems of retrospective study. Some data were not completely noted in the medical record e.g. AL may occur several days before the AL was clinically recognized, or the treatment of AL including type of operations were at in-charge surgeon's decision which may be not fully described. Second, only operations for colorectal cancer were included in this study. The incidence of AL and its presentation in benign colorectal operation needs to be studied. Third, this study focused on clinical or symptomatic AL. There might be several cases with subclinical AL or asymptomatic AL detected by radiological imaging. Fourth, there was no comparison of clinical presentations

and surgical outcomes between patients with early leakage (within 7 days after an operation) and their counterparts. Fifth, samples of infected tissue or intraabdominal collection were subjected to bacterial culture and test for antibiotics susceptibility in only two-third of AL cases. Lastly, this study did not cover the analysis of risk factors for AL-which is another area of interests to surgeons and of great clinical importance. Nevertheless, this study comprehensively described about the incidence, presentation, bacteriology, treatment and outcome of AL following colorectal surgery in Thailand-which could be a platform for developing diagnostic strategies and therapeutic approaches to AL of the lower gastrointestinal tract.

Conclusion

This study demonstrated that AL occurred in 1.9% of overall colorectal cancer operations with gastrointestinal anastomosis. It was commonly diagnosed on postoperative day 3 to 7, and about 13% of AL were found after patients were discharged. A high index of suspicion is a key for early diagnosis of AL especially in those with postoperative ileus, fever and oliguria. Peritonitis may be a late sign of AL. AL following colorectal surgery was associated with a high incidence of morbidity, mortality, re-operation and stoma formation. Apart from early diagnosis and adequate source control for AL, intravenous board-spectrum antibiotics covering both ESBL-producing *Enterobacteriaceae spp* and *Enterococcus spp*. should be administrated as an empirical therapy due to the high prevalence of these pathogens in AL cases.

What is already known on this topic?

Anastomosis leakage (AL) in colorectal cancer surgery is associated with high morbidity, risk of permanent stoma, prolonged hospitalization and even perioperative death. Patients with AL also have more cancer recurrence.

What this study adds?

This study demonstrated that anastomosis leakage (AL) was commonly diagnosed on postoperative day 3 to 7, and 13% of AL occurred after patients were discharged-thus raising the importance of detailed advice to patients and their family regarding early warning symptoms and signs of AL. Postoperative ileus, fever and oliguria were common manifestations suggesting of AL. This study also confirmed the high incidence of morbidity and mortality in patients with AL as most cases required surgical treatment and stoma formation. It resulted in 11% in-hospital mortality. Antimicrobial-resistant bacteria were identified in about one-third of AL cases.

Potential conflicts of interest

The authors declare no conflicts of interest.

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ภาวะรอยต่อลำไส้รั่วหลังผ่าตัดลำไส้ใหญ่และไส้ตรง 4,357 ราย: อุบัติการณ์ อาการและอาการแสดงทางคลินิก เชื้อแบคทีเรียก่อโรค วิธีการรักษาและผลลัพธ์

วรุตม์ โล่ห์สิริวัฒน์, ชาญวิทย์ อัศวศิริศิลป์

วัตถุประสงค์: งานวิจัยนี้ต้องการประเมินเพื่อศึกษาถึงอุบัติการณ์ อาการและอาการแสดงทางคลินิก เชื้อแบคทีเรียก่อโรค วิธีการรักษาและผลลัพธ์ของภาวะรอยต่อลำไส้รั่วหลังผ่าตัดลำไส้ใหญ่และไส้ตรง

วัสดุและวิธีการ: งานวิจัยนี้เป็นการศึกษาแบบย้อนหลังของผู้ป่วยที่มีภาวะรอยต่อลำไส้รั่วหลังผ่าตัดลำไส้ใหญ่และไส้ตรง ระหว่างปี พ.ศ. 2547 ถึง พ.ศ. 2558 ที่คณะแพทยศาสตร์ศิริราชพยาบาล

ผลการศึกษา: มีผู้ป่วยที่มีภาวะรอยต่อลำไส้รั่วทั้งสิ้น 84 รายจากการผ่าตัดมะเร็งลำไส้ใหญ่และไส้ตรงทั้งหมด 4,357 คน คิดเป็นร้อยละ 1.9 โดยพบการรั่วหลังผ่าตัดลำไส้ใหญ่ด้านขวาร้อยละ 1.4 หลังผ่าตัดลำไส้ใหญ่ด้านซ้ายร้อยละ 1.1 หลังผ่าตัดลำไส้ใหญ่ส่วนคดร้อยละ 2.1 และผ่าตัดไส้ตรงร้อยละ 2.4 ภาวะรอยต่อลำไส้รั่วส่วนใหญ่ได้รับการวินิจฉัยหลังผ่าตัดวันที่ 3 ถึง 7 (พบในวันที่ 4 มากที่สุด) มีผู้ป่วย 11 ราย (ร้อยละ 13) ได้รับการวินิจฉัยรอยต่อลำไส้รั่วหลังผู้ป่วยกลับบ้าน อาการนำที่สำคัญที่พบบ่อย ได้แก่ ภาวะลำไส้ไม่เคลื่อนไหว (ร้อยละ 80) ไข้ (ร้อยละ 76) และปัสสาวะน้อย (ร้อยละ 74) สำหรับอาการเยื่อบุช่องท้องอักเสบเฉพาะที่และอักเสบช่องท้องทั้งหมดพบร้อยละ 29 และร้อยละ 13 นอกจากนี้ยังพบว่าผู้ป่วยร้อยละ 13 มีภาวะสัญญาณชีพไม่คงที่ด้วย ผู้ป่วย 67 ราย (ร้อยละ 80) รักษาภาวะรอยต่อลำไส้รั่วด้วยการผ่าตัดและสร้างทวารเทียมทางหน้าท้อง ผู้ป่วย 9 ราย (ร้อยละ 11) เสียชีวิต และผู้ป่วย 63 (ร้อยละ 75) มีภาวะแทรกซ้อนหลังรักษาภาวะรอยต่อลำไส้รั่ว โดยเฉพาะแผลผ่าตัดติดเชื้อและหนองตกค้างในช่องท้อง ระยะเวลาการรักษาตัวในโรงพยาบาลเฉลี่ย 30 วัน ผลการเพาะเชื้อพบ *Escherichia spp.* บ่อยที่สุดและพบเชื้อดื้อยาที่สร้าง Extended-spectrum beta-lactamase ร้อยละ 31

สรุป: ภาวะรอยต่อลำไส้รั่วหลังผ่าตัดลำไส้ใหญ่และไส้ตรง แม้จะพบน้อยในการศึกษานี้แต่มีความสัมพันธ์กับภาวะแทรกซ้อนและการเสียชีวิตหลังผ่าตัดค่อนข้างสูง ผู้ป่วยส่วนใหญ่ต้องได้รับผ่าตัดร่วมกับการมีทวารเทียมทางหน้าท้อง