

## (Original Article)

## The Prevalence and Risk Factors of Gastrointestinal Anastomosis Leakage: A Retrospective Study

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(Received : 11 June 2021, Revised : 12 July 2021, Accepted : 30 July 2021)

### Abstract

**Objective :** The prevalence of gastrointestinal anastomosis leakage in patients underwent surgery in Bhumibol Adulyadej Hospital is evaluated as a primary outcome and risk factors of anastomosis leakage are investigated as secondary outcome.

**Method :** Retrospective review medical records of patients who underwent surgery between September 2012 and September 2016, patients with gastrointestinal anastomosis were included in the study. The prevalence of leakage in each site of anastomosis were records. The variables related to patient, Nutritional status, operation, surgical procedure and technique were analyzed as risk factors.

**Results :** 425 patients underwent surgery with gastrointestinal anastomosis were included. Anastomosis leakage was occurred in 25 (5.9 %) patients. The leakage rate was very in different site of anastomosis. There were 16 % of patients had postoperative leakage in esophageal anastomosis, 5.3 % in gastric anastomosis, 5.2 % in small bowel anastomosis leakage, 5.1 % in large bowel anastomosis, 4.1 % in small bowel-large bowel anastomosis and 6.6 % in rectal anastomosis. In multivariate analysis, pre-operative albumin level < 3.0 mg/dL (P=0.03, OR=2.647, 95 %CI=1.082-6.477) and smoke (P=0.001, OR=4.087, 95 %CI=1.717-9.692) were risk factor for leakage but surgical technique with hand sewn two layer was the only protective factor (P=0.001, OR=0.215, 95 %CI=0.077-0.579).

**Conclusion :** The prevalence of gastrointestinal anastomosis leakage in this study was 5.9 %, it was comparable to previous study. Pre-operative hypoalbuminemia and smoking patients were important risk factors for gastrointestinal anastomosis leakage. Hand sewn two-layer was safe rather than hand sewn one-layer technique for create gastrointestinal anastomosis.

**Keywords :** Risk factor, gastrointestinal anastomosis leakage.

Royal Thai Air Force Medical Gazette, Vol. 67 No. 1 January - April 2021

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(นิพนธ์ต้นฉบับ)

## การศึกษาอัตราการเกิดการรั่วของรอยต่อและปัจจัยเสี่ยงในการเกิดการรั่ว ของการผ่าตัดทางเดินอาหาร

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### บทคัดย่อ

**วัตถุประสงค์ :** เพื่อหาอัตราการเกิดการรั่วของรอยต่อและปัจจัยเสี่ยงในการเกิดการรั่วของการผ่าตัดทางเดินอาหาร

**วิธีการศึกษา :** เป็นการศึกษาแบบวิเคราะห์เปรียบเทียบข้อมูลในผู้ป่วยที่ได้รับรักษาโดยการผ่าตัดทางเดินอาหารและมีการต่อทางเดินอาหารในโรงพยาบาลภูมิพลอดุลยเดช ตั้งแต่เดือนกันยายน พ.ศ. 2555 ถึงเดือนกันยายน พ.ศ. 2559 โดยศึกษาเพื่อหาอัตราการเกิดการรั่วของรอยต่อของการผ่าตัดทางเดินอาหาร รวมถึงเปรียบเทียบปัจจัยเสี่ยงในกลุ่มที่การรั่วของรอยต่อเมื่อเทียบกับกลุ่มที่ไม่มีการรั่ว โดยใช้ปัจจัยเสี่ยงที่เกี่ยวข้องได้แก่ ข้อมูลพื้นฐาน, ข้อมูลทางภาวะโภชนาการ, ตำแหน่งของรอยต่อและเทคนิคในการต่อ

**ผลการศึกษา :** มีผู้ป่วยในการศึกษาทั้งหมด 425 ราย ได้รับการรักษาโดยการผ่าตัดทางเดินอาหารและมีการต่อทางเดินอาหารในโรงพยาบาลภูมิพลอดุลยเดช โดยมีผู้ป่วย 25 ราย ที่ติดเชื้อในแผลต่อหลังผ่าตัด คิดเป็น 5.9 % อัตราการเกิดการรั่วของรอยต่อมีความแตกต่างกันในแต่ละตำแหน่งของรอยต่อ โดยรอยต่อของหลอดอาหารมีการรั่ว 16 % รอยต่อของกระเพาะอาหารมีการรั่ว 5.3 % รอยต่อของลำไส้เล็กมีการรั่ว 5.2 % รอยต่อของลำไส้ใหญ่มีการรั่ว 5.1 % รอยต่อของลำไส้เล็กกับลำไส้ใหญ่มีการรั่ว 4.1 % รอยต่อของลำไส้ตรงมีการรั่ว 6.6 % โดยปัจจัยเสี่ยงที่ทำให้เกิดการรั่วของรอยต่อได้แก่ ค่าอัลบูมินในเลือดก่อนผ่าตัดน้อยกว่า 3 มิลลิกรัม/เดซิลิตร ( $P=0.03$ ,  $OR=2.647$ ,  $95\%CI=1.082-6.477$ ) และการสูบบุหรี่ ( $P=0.001$ ,  $OR=4.087$ ,  $95\%CI=1.717-9.692$ ) การต่อลำไส้แบบ 2 ชั้นจะช่วยลดการรั่วของรอยต่อเมื่อเทียบกับการต่อลำไส้แบบชั้นเดียว ( $P=0.001$ ,  $OR=0.215$ ,  $95\%CI=0.077-0.579$ )

**คำสำคัญ :** ปัจจัยเสี่ยง, การรั่วของรอยต่อของการผ่าตัดทางเดินอาหาร

### Introduction

Anastomosis leakage is the serious complication that associated with high morbidity and mortality. From previous study, rate of anastomosis leakage respectively is 3.9-15 %<sup>(1-5,10-13)</sup>. Increased morbidity, mortality, length of hospital stays, and cost are consequence of gastrointestinal anastomosis leakage<sup>(10-11)</sup>.

From previous data, many factors were analyzed to be potential risk factor for anastomosis leakage but there was controversial in some factor. Many previous studies that focused on leakage from colorectal surgery but only one study that evaluated entire gastrointestinal tract surgery.

Primary objective of this study is to evaluate the prevalence of gastrointestinal anastomosis leakage and the secondary aim is to investigate the risk factors of anastomosis leakage with using multivariate regression model.

### Patient and methods

This study is a retrospective descriptive study that focuses on gastrointestinal anastomosis leakage and its risk factors. The medical records of patients who underwent surgery with gastrointestinal anastomosis in the department of surgery in Bhumibol Adulyadej Hospital between September 2012 - September 2016 were analyzed.

All patients with gastrointestinal anastomosis were included and the patients who referred from another hospital were excluded. This study was approved by Bhumibol Adulyadej Hospital's research ethic committee.

Gastrointestinal anastomosis divided in esophageal anastomosis, gastric anastomosis, small bowel anastomosis, large bowel anastomosis, small bowel-large bowel anastomosis and rectal anastomosis. Gastrointestinal anastomosis leakage was defined as any defect in gastrointestinal wall integrity at the site of surgery that diagnosed by physical finding, radiologic finding (abscess or collection adjacent to anastomosis site) or intra-operative finding.

The prevalence of gastrointestinal anastomosis leakage was recorded. The demographic data of patients were collected and analyzed. Potential risk factors for anastomosis leakage divided into two group, factor related to patient: gender, age, ASA classification, underlying disease, patient BMI, patient's nutritional status, history of smoking, pre-operative serum albumin and factors related to operation: type of operation (elective or emergency), intra-operative blood loss, intra-abdominal contamination, surgical technique (hand sewn one layer, hand sewn two layers, instrument)

The nutritional status of patients was evaluated by Bhumibol nutritional triage (BNT) score, that divided severity into mild, moderate and severe malnutrition<sup>(6-8)</sup>.

### Statistical analysis

The data were analyzed with PASW (Predictive Analytics Soft Ware) Statistics 18. Mean was expressed for continuous variables and percentage was expressed for categorial variables in demographic data. The variable factors between two

group, leak and no leak, were compared using Pearson chi-square test and shown in odd ratio and p-value. P-value <0.05 was considered to indicated statistic significant. All variables with p < 0.05 in univariable analysis were included in the multivariable analysis using logistic regression analysis.

### Result

From September 2012-September 2016, 425 patients underwent surgery with gastrointestinal anastomosis were included. Two patients were excluded due to referred patient. Finally, 423 patients were in the study.

The demographic data of patients were shown in table 1. Mean age of patient was 64.14 (95 %CI 62.62-65.65). There were 243 males (55.3 %) and 189 females (44.7 %). 194 patients were in ASA class II (45.9 %), 187 patients were in ASA class III (44.2 %) and 42 patients were in ASA class I and IV (9.9 %). Mean BMI of patient was 24.05 (95 %CI 23.02-25.08). 375 patients were mild malnutrition (88.7 %) and 48 patients were moderate-severe malnutrition (11.3 %).

Table 1: patient characteristics

Characteristics of the patient	
Age	
< 65	198 (46.8%)
≥ 65	225 (53.2%)
Mean (95%CI)	64.14 (62.62-65.65)
Gender	
Male	243 (55.3%)
Female	189 (44.7%)
DM	92 (21.7%)
Smoking	
Yes	118 (27.9%)
No	305 (72.1%)
ASA classification	
Class I	17 (4%)
Class II	194 (45.9%)
Class III	187 (44.2%)
Class IV	25 (5.9%)
BMI	
< 25	300 (70.9%)
≥ 25	117 (27.7%)
Mean (95%CI)	24.05 (23.02-25.08)
BNT score	
mild malnutrition	375 (88.7%)
moderate – severe malnutrition	48 (11.3%)

**Table2 : Prevalence of gastrointestinal anastomosis leakage**

Anastomosis (total)	leak (%)	95 %CI
Esophageal anastomosis (31)	5 (16.1 %)	12.5-19.7
Gastric anastomosis (38)	2 (5.3 %)	3.1-7.5
Small bowel anastomosis (77)	4 (5.2 %)	3.0-7.4
Large bowel anastomosis (79)	4 (5.1 %)	3.0-7.2
Small bowel-Large bowel anastomosis (121)	5 (4.1 %)	2.2-6.0
Rectal anastomosis (77)	5 (6.5 %)	4.1-8.9
Total (423)	25 (5.9 %)	3.6-8.2

The prevalence of anastomosis leakage from this study was 5.9 %. The number of anastomosis leakage event in each site of anastomosis was as follows: esophageal anastomosis 5 (16.1 %, 95 %CI 12.5-19.7), gastric anastomosis 38 (5.2 %, 95 %CI 3.0-7.4), large bowel anastomosis 4 (5.1 %, 95 %CI 3.0-7.2), small bowel-large bowel anastomosis 5 (4.1 %, 95 %CI 2.2-6.0) and rectal anastomosis 5 (6.5 %, 95 %CI 4.1-8.9) as shown in table 2.

Statistically significant factors in leak group were smoking (15 VS 10, p<0.001, odd 4.296, 95 %CI

1.871-9.862) and pre-operative hypoalbuminemia < 3 gm/dL (10 VS 15, p=0.025, odd 2.530, 95 %CI 1.097-5.837). There was no statistically significant different in gender, age, ASA classification, DM, BMI or BNT score for nutritional status between leak and no leak group. Surgical technique with hand sewn two-layers and using instrument was shown to be protective factor for anastomosis leakage compared to one-layer hand sewn technique with odd ratio of 0.215 (P=0.001) and 0.283 (P=0.037) ordinally as shown in table 3.

**Table 3: Univariate analysis Risk factor for anastomosis leakage**

Factor relate to patient	Leak	Without leak	P-value	OD ratio	95 %CI
Gender					
Male	15 (6.4 %)	2.9 (93.6 %)	0.627	1.226	0.538-2.795
Female	10 (5.3 %)	179 (94.7 %)			
Age					
< 65	13 (6.2 %)	185 (93.4 %)	0.592	0.802	0.357-1.800
≥ 65	12 (5.7 %)	213 (94.7 %)			
ASA classification					
Class I-II	13 (6.2 %)	198 (93.8 %)	0.827	0.914	0.407-2.052
Class III-IV	12 (5.7 %)	200 (94.3 %)			
DM					
Yes	2 (2.2 %)	90 (97.8 %)	0.086	0.298	0.069-1.286
No	23 (6.9 %)	308 (93.1 %)			

## ตารางที่ 3 : (Cont.)

Factor relate to patient	Leak	Without leak	P-value	OD ratio	95 %CI
BMI					
< 25	18 (6 %)	282 (94 %)	0.995	1.003	0.408-2.468
≥ 25	7 (6 %)	110 (94 %)			
Malnutrition: BNT score					
mild (NT 1-2)	21 (5.6 %)	354 (94.4 %)			
moderate – severe (NT 3-4)	4 (8.3 %)	44 (91.7 %)	0.450	1.532	0.503-4.670
Smoking					
Yes	15 (12.7 %)	103 (87.3 %)	<0.001*	4.296	1.871-9.862 **
No	10 (3.3 %)	295 (96.7 %)			
Pre-operative serum albumin					
< 3 mg/dL	10 (10.8 %)	83 (89.2 %)	0.025*	2.530	1.097-5.837**
≥ 3 mg/dL	15 (4.5 %)	315 (95.5 %)			
Operation					
Elective	18 (72 %)	275 (69.1 %)	0.760	1.150	0.468-2.825
Emergency	7 (28 %)	123 (30.9 %)			
Intra-operative blood loss					
< 500	16 (5.2 %)	292 (94.8 %)	0.307	1.550	0.665-3.612
≥ 500	9 (7.8 %)	106 (92.2 %)			
Intra-abdominal contamination					
Yes	4 (9.3 %)	39 (90.7 %)	0.320	1.753	0.573-5.369
No	21 (5.5 %)	359 (94.5 %)			
Surgical technique					
Hand sewn one layer	17 (77.3 %)	133 (88.7 %)	reference	reference	reference
Hand sewn two layers	5 (22.7 %)	182 (57.8 %)	0.001	0.215	0.077-0.579
Instrument	3 (3.5 %)	83 (96.5 %)	0.037	0.283	0.080-0.995

After using multi-variate analysis, as shown in table 4, smoking and pre-operative hypoalbuminemia were still statistically significant factors for anastomosis leakage with odd ratio 4.080 ( $p=0.001$ , 95 %CI 1.717-9.692) and 2.647 ( $p=0.003$ , 95 %CI 1.082-6.477). Hand sewn two-layer was still shown to be protective factor with odd ratio 4.386 ( $p=0.006$ , 95 % CI 1.529-12.585).

From table 5 shown number of leakages in each anastomotic site and surgical technique. Hand sewn double layer technique seemed to have low rate of leakage but cannot analyze risk factor in each site of anastomosis due to low incidence of leakage.

**Table 4 : Multi-variate analysis Risk factor for anastomosis leakage**

Factors	Odds ratio	95 %CI	P-value
Pre-operative serum albumin (<3 mg/dL)	2.647	1.082-6.477	0.033
Smoking	4.080	1.717-9.692	0.001
DM	0.350	0.078-1.567	0.170
BMI (<25)	1.167	0.445-3.057	0.754
BNT score (3-4)	1.877	0.570-6.174	0.300
Surgical technique			
Hand sewn one layer	reference	N/A	N/A
Hand sewn two layers	4.386	1.529-12.585	0.006
Instrument	1.418	0.316-6.366	0.649

**Table 5 : Prevalence of leakage in each anastomotic site and surgical technique**

Anastomosis site	Surgical technique	Leak (%)	No leak (%)
Esophageal anastomosis	Hand sewn one layer	5 (22.7)	17 (77.3)
	Hand sewn two layers	0 (0)	1 (100)
	Instrument	0 (0)	8 (100)
Gastric anastomosis	Hand sewn one layer	1 (33.3)	2 (66.7)
	Hand sewn two layers	1 (4)	24 (96)
	Instrument	0 (0)	10 (100)
Small bowel anastomosis	Hand sewn one layer	3 (17.6)	14 (82.4)
	Hand sewn two layers	1 (1.7)	57 (98.3)
	Instrument	0 (0)	2 (100)
Large bowel anastomosis	Hand sewn one layer	2 (5.3)	36 (94.7)
	Hand sewn two layers	2 (6.5)	29 (93.5)
	Instrument	0 (0)	10 (100)
Small bowel – large bowel anastomosis	Hand sewn one layer	4 (10.5)	34 (89.5)
	Hand sewn two layers	1 (1.6)	62 (98.4)
	Instrument	0 (0)	20 (100)
Rectal anastomosis	Hand sewn one layer	2 (6.3)	30 (93.8)
	Hand sewn two layers	0 (0)	9 (100)
	Instrument	3 (8.3)	33 91.7)

## Discussion

In this study, the leakage rate of gastrointestinal anastomosis was 5.9 %. Previous studies, anastomosis leakage was range between 3-15.4 %, there were colon or rectal resection, where as only one study included all gastrointestinal tract anasto-

mosis, the anastomosis leakage was 15.4 %. Because of lack of a clear definition for anastomosis leakage, rate of leakage was various.

From this study, two variables were found to be risk factors for leakage. Similarly, to previous study smoking and pre-operative hypoalbuminemia

were risk factor for leakage with odd ratio of 4.29 (P<0.001) and 2.53 (P=0.025) ordinarily.

Smoking had proven to be in dependent risk factor for leakage in several studies, Hamed Ahmed et al.<sup>(1)</sup>, M. Parthasarathy et al.<sup>(3)</sup> and McDermott FD et al.<sup>(4)</sup>, which include only small bowel, large bowel or both.

Nutritional status was an important factor, which contributed to anastomosis leakage. In the study, pre-operative hypoalbuminemia was found to be significantly associated with an increased risk of leakage. It's same result from the study by M. Parthasarathy et al.<sup>(3)</sup>, Matteo frasson et al.<sup>(2)</sup>, and McDermott FD et al.<sup>(4)</sup>. The nutritional status improvement should be recommended in these patients to reduce the risk anastomosis leakage.

In the current study, Hand sewn two-layer was protective factors for leakage with odd ratio of 0.21 (P= 0.001) compared to Hand sewn one-layer and using instrument. The study by J. Segelman et al.<sup>(5)</sup>, there was no difference in anastomosis leakage between use of stapler or hand sewn anastomosis, but the they studied only in ileocolic and ileorectal anastomosis. Further study in each surgical technique and in each anastomotic site are need.

Male gender, underlying disease of DM, high ASA classification, and intra operative blood loss were not risk factors for leakage significantly, this finding was different from previous study<sup>(1-5,9,12-13)</sup>. It's may due to low incidence of anastomosis leakage in this study so the result cannot identify these risk factors.

Being a retrospective analysis, the present study has several limitations. First, only the patients who were clinically suspected of leakage underwent further examination or management. For this

reason, patients with subclinical anastomosis leakage were not diagnosed, which may underestimate the anastomosis leakage rate. Second, difference site of anastomosis may be different in risk factor for leakage. Finally, the low incidence of anastomosis leakage in each type of anastomosis site, so this study can't evaluate risk factor in each type.

## Conclusion

The prevalence of gastrointestinal anastomosis leakage in Bhumibol Adulyadej Hospital was 5.9 %, it was same range to previous study. Pre-operative hypoalbuminemia and smoking patients were important risk factors for gastrointestinal anastomosis leakage. Hand sewn two-layer was safe rather than hand sewn one-layer technique for create gastrointestinal anastomosis.

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