Original Article
Clavien-Dindo classification and risk factors of gastrectomy-related complications: an analysis of 1049 patients

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Abstract: Objective: The objective of the present study was to explore the major risk factors of surgical complications using the Clavien-Dindo classification. Methods: The case-control design was used. A total of 1049 patients who underwent radical gastrectomy in Hunan Cancer Hospital between October 2010 and August 2014 were retrospectively analyzed, including 122 patients (11.6%) with complications and 927 patients (88.4%) with no complications. Risk factors were evaluated. Results: Following radical gastrectomy, 122 patients (11.6%) experienced a total of 151 complications. The incidence of Stages II, IIIa, IIIb, IVa, IVb and V complications was 9.6% (n = 101), 2.5% (n = 26), 1.0% (n = 11), 0.8% (n = 8), 0% (n = 0), and 0.5% (n = 5), respectively. The incidence of severe complications (Stage $\geq$ IIIa) was 4.8% (n = 50). Multivariate analysis showed that combined resection (Odds Ratio [OR] = 3.36, 95% confidence interval [CI]: 1.71~6.60, P < 0.01), perioperative blood transfusion (OR = 2.13, 95% CI: 1.38-3.29, P < 0.01), and BMI $\geq$ 25 kg/m^2 (OR = 1.98, 95% CI: 1.16-3.40, P = 0.01) were independent risk factors of complications. Conclusions: Combined resection, perioperative blood transfusion, and BMI $\geq$ 25 kg/m^2 are positively correlated with complications.

Keywords: Gastric cancer, gastrectomy complications, Clavien-Dindo classification

Introduction

Gastric cancer represents a global health problem and is the third most frequently diagnosed cancer in men and the fifth in women [1]. A total of 989,600 new cases and 738,000 deaths are estimated to have occurred in 2008. Radical gastrectomy is the only treatment option available. With advances in surgical techniques and perioperative management, the incidences of death and complications are decreasing but unfortunately remain unacceptably high at 17.9-40.1% [2-5]. Anastomotic fistulas and intra-abdominal infections are the most common problems, adversely affecting disease-free survival (DFS) [6]. In spite of extensive investigations into surgical complications and survival-related risk factors, diagnostic criteria are diverse and the severity of complications are not well classified in many studies, making it impossible to make comparisons and evaluations between published reports. The Clavien-Dindo classification, first proposed by Dindo et al. [7] in 2004 has been widely used to evaluate systematically the severity of complications of many types of abdominal surgery [8, 9] except for radical gastrectomy [4, 5]. In the present study, the Clavien-Dindo classification was used to classify the complications associated with radical gastrectomy and to document major risk factors.

Patients and methods

Patients

Patients undergoing radical gastrectomy in the Hunan Cancer Hospital between October 2010

and August 2014 were retrospectively analyzed. Those patients with incomplete clinical data who had been operated on a second time for recurrence or did not reach the D2 standard were excluded from the study. A total of 1049 patients were deemed eligible, accounting for 82.7% of all patients (n = 1268) with gastric cancer, who underwent surgery. The cohort of patients comprised 681 men and 368 women, with an average age of 54.5 ± 10.3 years (range 19 to 81 years). Of these, 304 had co-existing diseases, including chronic hepatic diseases (hepatic cirrhosis, active viral hepatitis and fatty liver, n = 148), primary hypertension (*n* = 79), chronic obstructive pulmonary disease (COPD) (*n* = 35), cardiac diseases (coronary heart disease, severe arrthymia and valvular disease, n = 38), diabetes mellitus (*n* = 30) and renal dysfunction (*n* = 21); 39 patients had two or more co-existing conditions. Of the cohort, 270 patients experienced stomach cancer complications, 168 with pyloric obstruction, 107 with bleeding, 5 with perforation and 10 with two of these conditions. Tumor was staged according to the 7th UICC (Union for International Cancer Control) TNM (Tumor-Lymph Node-Metastasis) Staging System of Gastric Cancer [10] (218 in Stage I, 210 in Stage II and 621 in Stage III). The location and macroscopic type of tumor and procedures and range of surgery were decided according to the third Japanese gastric cancer treatment guidelines [11] (722 in lower stomach, 186 in middle stomach, 85 in upper stomach and 85 across the stomach).

Surgical procedures

All patients underwent gastrectomy with either D2 or D2+ lymph node dissection. To re-establish the digestive tract, the Billroth I procedure was used for lower gastrectomy and the Billroth II procedure for those patients with duodenal involvement and ulcers. Those with upper and middle gastric cancer received a total gastrectomy and Roux-en-Y esophagojejunal anastomosis and in some patients also a P-loop to replace the stomach. Proximal gastrectomy was applied for upper early-stage cancer only involving the mucosa or submucosa but combined abdominal resection for advanced gastric cancer infiltrating adjacent regions but not distal organs. In total, 53 patients received proximal gastrectomy, 748 distal gastrectomy, 181 total gastrectomy and 67 had a combined

resection including 27 with two or more organs resected (19 with pancreas body and tail, and spleen resection, 5 with transverse colon and part pancreas resection, 2 with pancreaticoduodenectomy and 1 with combined left upper abdominal organ resection), and 40 patients with one organ resection (12 with transverse colon resection, 11 with part liver resection, 9 with spleen resection, 7 with part pancreas resection and 1 with left colectomy).

Grouping

Complications were identified and classified according to the Clavien-Dindo classification [4, 7]. After considering the clinical symptoms reported by many doctors, classification I was deemed to have no complications [12, 13]. Complications were detected in 122 subjects (11.6%) and none in 927 (88.4%). Clinical and pathological data were compared between patients, with and without complications, to analyze the major risk factors associated with complications.

Statistical analysis

SPSS (version 19.0; SPSS, Inc., Chicago, I L) was used for statistical analysis. First, the data was tested to determine if they were normally distributed. Data with a normal distribution were expressed as the mean ± standard deviation (SD), and compared using a *t*-test. Numeration data were expressed as a percentage (%) and compared using the χ^2 or the exact Fisher's test. Complication-related risk factors were screened using univariate analysis. Statistically significant variables with *P* < 0.1 were further analyzed using multivariate logistic regression. The OR and 95% confidence interval (CI) were calculated. *P* < 0.05 (bilateral) was considered to be statistically significant.

Results

Clinical data

The clinical data are shown in **Table 1**. The incidence of complications was 11.6% (*n* = 122). Five patients died from respiratory failure, cerebral infarction, acute myocardial infarction, cardiac arrest and multiple organ dysfunctions respectively. Of the subjects, 87 had local complications (34 with abdominal infection; 16 with anastomotic fistula and intestinal obstruction) and 64 patients had systemic complications

Table 1. General data obtained from 1049 patients

Variable	N (%)
Age (years)	54.5 ± 10.3[a] (range19-81)
Male or female	681:368 (64.9%:35.1%)
BMI (kg/m^2)	21.6 ± 2.9[a]
Preoperative ASA	
1	127 (12.1%)
2	735 (70.1%)
3	177 (16.9%)
4	10 (1.0%)
History of abdominal surgery	
Yes	98 (9.3%)
No	951 (90.7%)
Co-morbidities	
Yes	304 (29.0%)
No	745 (71.0%)
New adjuvant chemotherapy	
Yes	36 (3.4%)
No	1013 (96.6%)
Surgical procedure	
Laparotomy	991 (94.5%)
Laparoscopically-assisted	58 (5.5%)
Surgical range	
Distal gastrectomy	748 (71.3%)
Proximal gastrectomy	53 (5.1%)
Total gastrectomy	181 (17.3%)
Combined resection	67 (6.4%)
Surgical time (minutes)	217.1 ± 51.4[a]
TNM staging	
I	218 (20.8%)
II	210 (20.0%)
III	621 (59.2%)
Perioperative blood transfusion	
Yes	256 (24.4%)
No	793 (75.6%)
Transferring to ICU post surgery	
Yes	54 (5.1%)
No	995 (94.9%)
Hospital stay post surgery (days)	14.1 ± 4.5[a] (range 7-49)
Clavien-Dindo classification	
II	101 (9.6%)
IIIa	26 (2.5%)
IIIb	11 (1.0%)
Iva	8 (0.8%)
IVb	0 (0%)
V	5 (0.5%)

ASA: American Society of Anesthesiologist, BMI: Body Mass Index, ICU: Intensive Care Unit. [a]mean ± SD.

(45 with lung infection, 5 with urinary infection and 4 with pulmonary infection) (**Table 2**).

Infection (abdominal and pulmonary infection) was the most common complication. The incidence of Stages II, IIIa, IIIb, IVa, IVb and V complications was 9.6% (n = 101), 2.5% (n = 26), 1.0% (n = 11), 0.8% (n = 8), 0% (n = 0), and 0.5% (n = 5), respectively. The presence of severe complications (≥ IIIa) that required invasive intervention was 4.8% (50/1049). Patients with complications had a longer surgical procedure (243.2 ± 58.6 min *versus* 213.4 ± 50.0 min, P = 0.04), more intraoperative blood loss (249.9 ± 152.9 mL *versus* 212.5 ± 133.6 mL, P = 0.01), more red cell transfusions during the surgical period (2.3 ± 4.0 U *versus* 1.1 ± 2.4 U, P < 0.01), longer gastric-tube dwelling period after surgery (3.8 ± 2.8 d *versus* 2.8 ± 1.9 d, P < 0.01), a higher proportion transferring into the Intensive Care Unit (ICU) post surgery (31.1% *versus* 1.7%, P < 0.01) and longer hospital stays post surgery (20.5 ± 8.6 d *versus* 13.3 ± 2.7 d, P < 0.01). Age, gender, body mass index (BMI), smoking, harvested lymph node, hemoglobin and albumin level at admission were not statistically different between patients with and without complications (All P > 0.05, **Table 3**).

Univariate analysis

Of all the clinical and pathological factors, the complications were most closely correlated with age ≥ 60 years, BMI ≥ 25 kg/m^2, co-existing diseases, American Society of Anesthesiologist (ASA) score ≥ 3, combined organ resection, surgical period ≥ 240 min, intraoperative blood loss ≥ 300 mL and intraoperative, post operative and perioperative transfusion (**Table 4**). The complications were not associated with the history of abdominal surgery, novel adjuvant chemotherapy, preoperative anemia, preoperative transfusion, laparoscope-assisted surgery or TNM Stage ≥ III (All P > 0.05, **Table 4**).

Multivariate analysis

Statistically significant variables in univariate analysis with P < 0.10 were further analyzed with multivariate logistic regression. Combined resection (OR = 3.36, 95% CI

Table 2. Local and systemic complication

Local infection	N (%)	Grade ≥ IIIa N (%)	Systemic complication	N (%)	Grade ≥ IIIa N (%)
Abdominal infection	34 (3.2%)	8 (0.8%)	Pulmonary infection	45 (4.3%)	9 (0.9%)
Anastomotic fistula	16 (1.5%)	5 (0.47%)	Urinary infection	5 (0.47%)	0
Intestinal obstruction	14 (1.3%)	6 (0.57%)	Pleural effusion	4 (0.38%)	3 (0.29%)
Abdominal hemorrhage	5 (0.47%)	3 (0.29%)	Pneumothorax	3 (0.29%)	2 (0.2%)
Abdominal effusion	4 (0.38%)	3 (0.29%)	Renal failure	2 (0.2%)	2 (0.2%)
Gastrointestinal hemorrhage	3 (0.29%)	0	Diabetic ketoacidosis	1 (0.1%)	1 (0.1%)
Disruption of wound	3 (0.29%)	3 (0.29%)	Cardiac arrest	1 (0.1%)	1 (0.1%)
Lymphatic fistula	3 (0.29%)	0	Cardiac infarction	1 (0.1%)	1 (0.1%)
Pancreatic fistula	2 (0.2%)	0	Cerebral infarction	1 (0.1%)	1 (0.1%)
Duodenal stump fistula	2 (0.2%)	0	Multiple organ dysfunction	1 (0.1%)	1 (0.1%)
Anastomotic stricture	1 (0.1%)	1 (0.1%)			
Total	87 (8.3%)	29 (2.8%)	Total	64 (6.1%)	21 (2.0%)

Table 3. Comparison of clinical data from 1049 patients (%, Mean ± SD)

	Complications (N = 122)	No complications (N = 927)	χ^2/t	P value
Sex			0.32	0.57
Male	82 (67.2%)	599 (64.6%)		
Female	40 (32.8%)	328 (35.4%)		
Age (year-old)	57.3 ± 9.8	54.1 ± 10.4	1.13	0.29
BMI (kg/m^2)	22.2 ± 3.1	21.5 ± 2.9	1.93	0.17
Smoker			2.42	0.12
Yes	57 (46.7%)	365 (39.4%)		
No	65 (53.3%)	562 (60.6%)		
Lymph nodes dissected (n)	19.8 ± 7.7	18.9 ± 8.0	0.13	0.71
WBC (× 10^9/L)	6.0 ± 1.7	6.2 ± 2.1	0.45	0.50
Preoperative hemoglobin (g/L)	113.6 ± 24.5	117.2 ± 24.3	0.09	0.76
Preoperative albumin (g/L)	35.6 ± 5.3	36.9 ± 5.2	0.03	0.87
Surgical time (min)	243.2 ± 58.6	213.4 ± 50.1	4.27	0.04
Blood loss (mL)	249.9 ± 152.9	212.5 ± 133.6	6.25	0.01
Blood transfusion during the perioperative period (U)	2.3 ± 4.0	1.1 ± 2.4	37.13	< 0.01
Postoperative gastric tube (days)	3.8 ± 2.8	2.8 ± 1.9	8.37	< 0.01
Transferring to ICU post surgery			191.13	< 0.01
Yes	38 (31.1%)	16 (1.7%)		
No	84 (68.9%)	911 (98.3%)		
Hospital stays post surgery (days)	20.5 ± 8.6	13.3 ± 2.7	392.66	< 0.01

1.71-6.6), perioperative blood transfusion (OR = 2.13, 95% CI 1.38-3.29), and BMI ≥ 25 kg/m^2 (OR = 1.98, 95% CI 1.16-3.40) were independent risk factors associated with complications (**Table 5**). Combined resection and perioperative blood transfusion showed relatively high risk.

Discussion

The current study has shown that local and systemic infections remain the major complica-tions associated with radical gastrectomy. The incidence of Stage II to Stage V complications was 11.6%, in agreement with 12.4% reported by Lee et al. [5] and 14.3% by Lee et al. [4]. However, it was higher than the 8.1% reported by Tokunaga et al. [13] who selected early stage subjects who had only D1+ radical surgery and individuals who needed blood transfusions dur-ing the perioperative period. In the study by Hayashi et al. [12], the incidence was as high as 18%, possibly because all the 83 patients were

Table 4. Univariate analysis of risk factors of complications (Yes/No)

Variable	Complications (N = 122)	No complications (N = 927)	χ^2	P value
Age ≥ 60 years	58/64	301/626	10.88	< 0.01
BMI < 18 kg/m^2	7/115	92/835	2.21	0.14
BMI ≥ 25 kg/m^2	23/99	115/812	3.92	0.04
Co-morbidity	50/72	254/673	9.67	< 0.01
Complications	34/88	236/691	0.33	0.57
ASA ≥ 3	33/89	154/773	8.02	< 0.01
History of abdominal surgery	10/112	88/839	0.21	0.64
New adjuvant chemotherapy	3/119	33/894	0.39	0.79
Anemia (hemoglobin < 100 g/L)	30/92	201/726	0.53	0.47
Preoperative albumin < 30 g/L	14/108	78/849	1.26	0.26
Additional surgery#	6/116	32/895	0.66	0.42
Total gastrectomy	18/104	152/775	0.21	0.64
Combined resection	24/98	43/884	40.75	< 0.01
Laparoscopically-assisted	8/114	50/877	0.28	0.60
TNM Stage ≥ III	78/44	543/384	1.28	0.26
Surgical time ≥ 240 min	63/59	260/667	28.16	< 0.01
Blood loss ≥ 300 ml	49/73	239/688	11.20	< 0.01
Preoperative blood transfusion	17/105	92/835	1.86	0.17
Intra-operative blood transfusion	21/101	101/826	4.19	0.04
Postoperative blood transfusion	29/93	99/828	17.25	< 0.01
Perioperative blood transfusion	49/73	207/720	18.59	< 0.01

ASA (American Society of Anesthesiologists). #Cholecystectomy (n = 23), oophorocystectomy (n =7), myomectomy (n = 3), hepatic hemangioma resection (n = 3), single nephrectomy (n = 1), anterior resection of rectum (n = 1).

aged between 80 and 88 years old, and 60 (72%) of the patients had at least one co-morbidity. Of all the complications, grade II complications comprised the majority (66.9%), mainly attributed to infections (51.7%), consistent with previous reports in the literature [14]; these complications could be cured by the administration of appropriate antibiotics. In the present inquiry, the incidence of grade III complications (intestinal obstruction, abdominal hemorrhage and infection with inadequate drainage that required invasive surgery), grade IV complications (respiratory or renal failure requiring transfer to the ICU for respiratory support or dialysis), and grade V complications (death from respiratory or cerebrovascular accidents) were 4.8% (n = 50), consistent with 2.9-8.4% in the literatures [5, 12, 13] but significantly lower than the 14.3% reported by Lee et al. [4].

The logistic regression analysis showed that combined resection was the independent risk factor for surgical complications (OR 3.36, P < 0.01), with the reported incidence of complica-

tions being 11.8-90.5 % and a mortality of 0 to 15%, significantly higher than those patients who underwent single radical gastrectomy [15]. The results were in accordance with those of previously published studies [4, 16, 17]. The spleen, which plays a crucial role in releasing cytokines and immune factors, is frequently dissected in the combined procedures, unavoidably lowering immunological competence and increasing the risk of infection. Therefore, the combined procedure including removal of splenic hilar lymph nodes should be replaced by more exquisite lymph node resection as is practically possible. Moreover, combined resec-

tion, including the pancreatic body and tail as well as the spleen produced a risk of pancreatic fistula of 10.5% (2/19), resulting in severe abdominal infection due to extensive surgical trauma and blood loss, the prolonged surgery time a decrease in immunological functions. The results strongly suggest that unnecessary combined resection should be avoided, if at all possible. In addition, many scholars have found that accurate diagnosis of Stage T4 gastric cancer is troublesome and approximately half of the cases had to undergo combined resection owing to misdiagnosis of tissue adhesion due to tumor infiltration [18]. Hence, careful attention should be paid to peripheral tumor invasion during surgery and if necessary rapid pathological slices examined to try to avoid the need for combined resection.

In the present study, the incidence of complications increased by 113% in patients who received a blood transfusion during the perioperative period, compared to those who did not require a blood transfusion. The perioperative

Table 5. Logistic regression analysis of independent risk factors of complications

Variable	Odds Ratio [OR]	95% Confidence Interval [CI]	P value
Combined resection	3.36	1.71-6.60	< 0.01
Perioperative blood transfusion	2.13	1.38-3.29	< 0.01
Body Mass Index ≥ 25 kg/m²	1.98	1.16-3.40	0.01

transfusions indicated that the patients had been in a chronic bleeding status, which is an important risk factor for complications. Bernard et al. [19] summarized the results from 125,233 patients who underwent surgery and found that intraoperative transfusions of 1 U to 2 U packed red blood cells was associated with an increased 30-day mortality, surgical-site infection, pneumonia, and sepsis in general surgery patients after adjustment for transfusion propensity, incision classification and surgical time. With the advancement in surgical techniques and instrumentation, the proportion of patients requiring transfusion during the perioperative period continues to decrease. However, many patients still required a transfusion for the treatment of anemia due to hemorrhage or chronic dystrophy. In the present study, those patients (hemoglobin < 100 g/L) accounted for 22.0% (231/1049) of subjects and those requiring transfusion during the perioperative period accounted for 24.4%. It has been acknowledged that blood transfusion increases postoperative complications, especially the risk of patients developing infections. However, there is still no consensus regarding the volume or the time of blood transfusions (preoperative, intraoperative or postoperative) and its effects in eliciting complications. Mohri et al. [14] reported that intraoperative and postoperative but not preoperative blood transfusion were risk factors for hospital-acquired pneumonia. The present study confirmed intraoperative transfusion as an independent risk, regardless of the amount and the number of blood transfusions. Clearly, it will be necessary to investigate this important finding in larger scale clinical trials in the near future.

Compared to normal-weight patients, obese patients (BMI ≥ 25 kg/m²) had a significantly higher risk of acquiring abdominal infections following radical gastrectomy (*OR* = 1.98). Sugisawa et al. [20] also found that pancreas-related infection and anastomotic fistula occurred at a much greater incidence in obese patients, especially those with excessive visceral fat. The reasons are as follow: First, there are fewer blood vessels in fatty tissues, with consequent poor anti-infection and healing ability [21]. Second, pancreatic tissues are virtually indistinguishable from fatty tissues and the pancreas is susceptible to damage during lymph node dissection. Third, these patients are characterized with poor abdominal exposure and much more difficult operations, which inevitably lead to an increased operation time and blood loss. Lastly, it has been unequivocally established that obese patients are more likely to suffer from complications after surgery.

In conclusion, the Clavien-Dindo classification of postoperative complications is without doubt an important method to compare and evaluate the safety of radical gastrectomy. Decreasing perioperative blood losses and combined resection is beneficial in reducing the complications associated with radical gastric surgery.

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Disclosure of conflict of interest

None.

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