

Influence of Overweight on Surgical Complications for Gastric Cancer: Results From a Randomized Control Trial Comparing D2 and Extended Para-aortic D3 Lymphadenectomy (JCOG9501)

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Background: The impact of overweight on the outcome of gastrectomy with lymphadenectomy is controversial, and data from a well-controlled, randomized study are needed to identify a possible relationship.

Methods: We used data from 523 patients registered for a prospective randomized trial comparing D2 and extended para-aortic D3 lymphadenectomy to compare the effects of body mass index (BMI) and the extent of lymphadenectomy for the development of general or major surgical complications (anastomotic leakage, abdominal abscess, and pancreatic fistula).

Results: Seventy-seven patients were classified as overweight with BMI ≥ 25 , and 38 and 39 of these patients underwent a D2 or D3 lymphadenectomy, respectively. Among the 446 patients classified as nonoverweight with BMI < 25 , 225 received D2 and 221 received D3 lymphadenectomy. Surgical complications, operation time, and blood loss were statistically significantly associated with BMI, and logistic regression analysis revealed that overweight directly affected the occurrence of surgical complications even after considering operation time.

Received July 27, 2006; accepted July 27, 2006; published online December 5, 2006.

Members of the Gastric Cancer Surgery Study Group of Japan Clinical Oncology Group are listed in the Acknowledgments.

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and blood loss as intermediate factors instead of outcome variables. Among patients undergoing D2 lymphadenectomy, being overweight increased the risk for surgical complications and blood loss, whereas overweight was associated with only blood loss and operation time among patients receiving D3 lymphadenectomy.

Conclusions: Overweight increased the risk of surgical complications in patients undergoing gastrectomy both directly and indirectly through operation time and blood loss. The impact of overweight on surgical complications was more evident in patients undergoing a D2 dissection.

Key Words: Overweight—BMI—Complication—Gastric cancer—RCT—JCOG.

The incidence of overweight and obesity has been increasing in the general population, but the impact of overweight on surgical outcomes is unclear. Cancer surgery in overweight patients often takes longer and is associated with greater blood loss than in lean individuals as a result of the presence of excessive fat tissue impairing surgical procedures and lymph node dissection. The influence of overweight on the outcomes, e.g., surgical complications, surgical quality, hospital stay, and prognosis, of gastrectomy with D2 lymph node dissection for patients with gastric cancer is controversial.¹⁻⁵ These data were derived retrospectively from a single institution, but the surgical procedures and disease stages varied.

A prospective study from multiple institutions that use a similar surgical procedure is the ideal means to assess the impact of overweight on surgical outcomes and overall prognosis. A randomized trial, Japan Clinical Oncology Group (JCOG) 9501, was launched in 1995 to explore the potential survival benefit of extended para-aortic D3 dissection over standard D2 dissection. This trial provided the opportunity to prospectively evaluate collected data regarding the effect of overweight on surgical outcome after D2 or D3 dissection. Because a patient's physical condition, including body mass index (BMI), could affect treatment indications for either D2 or D3, an observational study may not correctly compare potential differences between groups. Thus, we used the JCOG data to investigate the interaction of D2/D3 dissection and overweight on surgical complications in a randomized trial. In addition, we examined whether overweight directly influences the occurrence of complications or if the effects of overweight may be mediated by associated factors, such as operation time and blood loss.

PATIENTS AND METHODS

Between June 1995 and April 2001, a total of 523 patients registered in the JCOG9501 study were randomly allocated to either D2 ($n = 263$) or D3

dissection ($n = 260$) by balancing the groups according to institution, tumor growth pattern (expansive vs. infiltrative growth) and tumor (T) stage (cT2b vs. cT3/cT4). Patients aged <76 years with histologically proven and resectable primary gastric carcinoma with an estimated depth of SS (invading subserosa: cT2b), SE (penetrating serosa: cT3), or SI (invading adjacent structures: cT4) were recruited after providing informed consent as described elsewhere.⁶ Patients with free cancer cells by cytological examination of peritoneal washes and those with type 4 tumor (linitis plastica type) were excluded.

Patients underwent appropriate gastrectomy with systematic lymphadenectomy as allocated by the study protocol. Perigastric lymph nodes (nodal station nos. 1, 3, 4, 5, and 6 according to the Japanese Classification of Gastric Cancer) and nodes at the base of the left gastric artery (no. 7), along the common hepatic artery (no. 8) and at the base of the splenic artery (no. 11) were routinely resected. Lymph nodes along the hepatoduodenal ligament and behind the pancreatic head (nos. 12 and 13) were resected when the primary lesion was located in the lower third of the stomach. Lymph nodes along the left side of the cardia (no. 2), within the splenogastric ligament (no. 4sa) and at the splenic hilum (no. 10), were resected with the spleen when total or proximal gastrectomy was performed. In patients randomized to a D3 lymphadenectomy group, para-aortic lymph nodes from the level of the celiac trunk down to the root of the inferior mesenteric artery (nos. 16a2 and 16b1) were dissected. The mode of reconstruction after resection was not specified.

Information on complications (including major surgical complications) and patient backgrounds (including height and body weight) was extracted from the case report forms for the trial. In this study, anastomotic leakage, pancreatic fistula, and abdominal abscess are defined as surgical complications. Anastomotic leakage was defined as dehiscence confirmed by radiographic examination that used contrast medium. Pancreatic fistula was diagnosed if

there was prolonged purulent discharge that contained pancreatic juice from the drainage tube. In addition, pneumonia and other complications were evaluated as complications.

According to the World Health Organization classification, BMI ≥ 25 is considered as overweight and BMI < 25 as nonoverweight.⁷ Factors that might affect the risk of overall and major surgical complications, such as sex, age, tumor location, pathological (p) T category (pT2 and pT3 vs. pT4), extent of lymphadenectomy, type of gastrectomy, splenectomy, and pancreatectomy were evaluated as potential confounding factors. The difference in the distribution of these factors between BMI < 25 and BMI ≥ 25 were examined by χ^2 test. The effect of overweight on the complications was evaluated by odds ratio. In addition, the effect of overweight on operating time, amount of blood loss, need for autologous blood transfusion, reoperation, and hospital death was also evaluated by odds ratio. Operating time, blood loss, and the number of retrieved lymph nodes were divided into tertiles as previously described⁸ and used as binary variables by dichotomizing the highest tertiles and the remaining two tertiles because biologically meaningful cutoff points could not be defined. In addition to the univariate analysis, all the analyses were conducted adjusting all the potential confounding factors by logistic regression.

To evaluate the effect of overweight on complications, logistic regression on the complications were conducted with overweight as exposure and operating time and blood loss as intermediate factors in addition to the other potential confounding variables. This analysis reveals whether overweight affects complications directly, or indirectly through these intermediate factors.

To see the difference of the effect of overweight between D2 and D3 dissection, all the analyses were repeated separately for the D2 and D3 subgroups, and these interactions were also evaluated. All statistical analyses were performed SAS software version 8.12 (SAS Institute, Tokyo, Japan). *P* values less than .05 were considered statistically significant, and all tests were two-sided.

RESULTS

Seventy-seven patients were classified as overweight with BMI ≥ 25 , and 38 and 39 of these patients underwent D2 or D3 lymphadenectomy, respectively. In 446 patients classified as nonoverweight with BMI

TABLE 1. Backgrounds of patients according to body mass index (BMI)

Factor	BMI < 25 (n = 446)	BMI ≥ 25 (n = 77)	Total number	<i>P</i> value
Sex				
M	301	57	358	.26
F	145	20	165	
Age				
< 56	137	23	160	.93
56-65	176	31	207	
> 65	133	23	156	
Location				
A (lower third)	188	29	217	.59
M (middle third)	173	33	206	
C (upper third)	85	15	100	
Clinical tumor stage				
cT2b	161	31	192	.38
cT3	268	41	309	
cT4	17	5	22	
Lymph node dissection				
D2	225	38	263	.86
D3	221	39	260	
Type of gastrectomy				
Distal	272	48	320	.82
Total/proximal	174	29	203	
Splenectomy				
No	283	49	332	.98
Yes	163	28	191	
Pancreatectomy				
No	427	74	501	.88
Yes	19	3	22	

< 25 , 225 received D2 and 221 received D3 lymphadenectomy. Total gastrectomy was performed in 199 (38.0%) of 523 patients and proximal gastrectomy in 4; the remaining patients underwent distal gastrectomy. Splenectomy was performed in 191 patients (36.5%) and distal pancreatectomy in 22 (4.2%). The background characteristics of patients with different BMIs are listed in Table 1. There were no statistically significant differences in sex, age, tumor location, clinical T stage, lymph node dissection, type of gastrectomy, and incidence of combined resection between the two groups, and the two groups were well balanced.

In the entire sample, any complications were identified in 128 patients (24.5%), and major surgical complications occurred in 49 patients (9.4%). Among overweight patients, however, the proportion developing either any or surgical complications was 35.1% and 19.5%, respectively. When assessed by univariate analysis, overweight statistically significantly increased the risk for pancreatic fistula, abdominal abscess, operation time, and blood loss (Table 2). Additionally, the number of retrieved lymph nodes was less in overweight patients. Multivariate analysis identified that overweight was significantly associated

TABLE 2. Effect of overweight on postoperative complications and other outcome variables^a

Factors	BMI < 25	BMI ≥ 25	Univariate analysis		Multivariate analysis	
			Odds ratio of BMI > 25 (95% CI)	P value	Odds ratio of BMI > 25 (95% CI)	P value
Operation time (min)						
> 297	141	36	1.90 (1.16–3.10)	.01	2.24 (1.29–3.87)	.004
≤ 297	305	41	–		–	
Blood loss (ml.)						
> 710	131	44	3.21 (1.95–5.26)	< .001	3.74 (2.19–6.39)	< .001
≤ 710	315	33	–		–	
Blood transfusion						
Yes	98	17	1.01 (.56–1.80)	.98	1.10 (.59–2.03)	.77
No	348	60	–		–	
No. of retrieved lymph nodes						
≤ 54	137	33	1.69 (1.03–2.77)	.037	1.82 (1.06–3.14)	.031
> 54	309	44	–		–	
Reoperation						
Yes	9	3	1.97 (.52–7.44)	.32	1.85 (.47–7.29)	.38
No	437	74	–		–	
Hospital death						
Yes	3	1	1.94 (.20–18.92)	.56	1.96 (.20–19.50)	.56
No	443	76	–		–	
Any complication						
Yes	101	27	1.84 (1.10–3.10)	.021	1.90 (1.11–3.24)	.019
No	345	50	–		–	
Surgical complication						
Yes	34	15	2.93 (1.51–5.69)	.002	3.35 (1.65–6.78)	< .001
No	412	62	–		–	
Anastomotic leak						
Yes	8	3	2.22 (.58–8.56)	.25	2.14 (.54–8.47)	.28
No	438	74	–		–	
Pancreatic fistula						
Yes	20	10	3.18 (1.43–7.09)	.005	4.18 (1.71–10.22)	.002
No	426	67	–		–	
Abdominal abscess						
Yes	19	10	3.35 (1.50–7.52)	.003	3.51 (1.52–8.12)	.003
No	427	67	–		–	
Pneumonia						
Yes	12	4	1.98 (.62–6.31)	.25	1.88 (.58–6.13)	.29
No	434	73	–		–	
Other complication						
Yes	65	11	0.98 (.49–1.95)	.95	0.97 (.48–1.95)	.93
No	381	66	–		–	

BMI, body mass index; 95% CI, 95% confidence interval.

^a Multivariate covariables: BMI, sex, age, tumor location, clinical tumor stage, lymph node dissection, type of gastrectomy, splenectomy, pancreatectomy.

with pancreatic fistula, abdominal abscess, operation time, and blood loss, and the odds ratios (95% confidence intervals) were 4.18 (1.71–10.22), 3.51 (1.52–8.12), 2.24 (1.29–3.87), and 3.74 (2.19–6.39), respectively. The number of retrieved lymph nodes decreased in overweight patients with an odds ratio of 1.82 (1.06–3.14). When operation time and blood loss were treated as intermediate factors, the odds ratios for the development of pancreatic fistula and abdominal abscess decreased to 3.48 and 2.47, respectively, but were still statistically significant.

We next analyzed the D2 (n = 263) and D3 (n = 260) dissection subgroups (Table 3). In the D2 subgroup, overweight was significantly associated with pancreatic fistula, abdominal abscess, and blood loss

with odds ratios (95% confidence intervals) of 4.74 (1.42–15.89), 4.72 (1.49–14.99), and 2.83 (1.33–6.04), respectively. In the D3 subgroup, only blood loss with an odds ratio of 5.05 (2.27–11.26) and operation time with an odds ratio of 2.27 were significantly associated with overweight, although the interaction P values between the D2 and D3 subgroups were not statistically significant for any of the factors examined.

DISCUSSION

We clearly showed that overweight patients are at increased risk for the development of organ/space

TABLE 3. Effect of overweight on postoperative complications and other outcome variables stratified with lymph node dissection (D2 or D3)^a

Factor	D2 subgroup (n = 263)		D3 subgroup (n = 260)		Interaction P value
	Multivariate odds ratio of BMI \geq 25 (95% CI)	P value	Multivariate odds ratio of BMI \geq 25 (95% CI)	P value	
Operation time					
Operation time > 297 min	2.19 (.96-5.02)	.063	2.27 (1.09-4.73)	.028	.95
Blood loss > 710 mL	2.83 (1.33-6.04)	.007	5.05 (2.27-11.26)	< .001	.30
Blood transfusion	1.73 (.70-4.26)	.23	0.78 (.34-1.79)	.56	.20
No. of retrieved lymph nodes \leq 54	2.73 (1.28-5.85)	.01	1.06 (.43-2.62)	.9	.12
Reoperation	4.21 (.64-27.61)	.13	0.82 (.09-7.39)	.86	.27
Hospital death	6.82 (.40-117.43)	.19	NE	.98	.94
Any complication	2.62 (1.23-5.61)	.013	1.39 (.65-2.98)	.4	.25
Surgical complications	4.20 (1.59-11.10)	.004	2.60 (.91-7.40)	.074	.51
Anastomotic leak	2.77 (.47-16.19)	.26	1.49 (.16-14.09)	.73	.67
Pancreatic fistula	4.74 (1.42-15.89)	.012	3.61 (.96-13.55)	.057	.77
Abdominal abscess	4.72 (1.49-14.99)	.009	2.55 (.73-8.85)	.14	.48
Pneumonia	2.81 (.79-10.04)	.11	NE	.97	.94
Other complications	1.08 (.34-3.37)	.9	0.91 (.37-2.23)	.83	.82

BMI, body mass index; NE, not able to estimate.

^a Covariables: BMI, sex, age, tumor location, clinical tumor stage, type of gastrectomy, splenectomy, pancreatectomy.

surgical site infection (SSI) (abdominal abscess and pancreatic fistula) complications after gastrectomy with D2 or D3 dissection. Risk factors for the development of SSI in abdominal surgery have been intensively investigated. The presence of a preoperative cutaneous abscess or necrosis, sutures or anastomoses of the bowel, postoperative abdominal drainage, surgical treatment for cancer, and postoperative anticoagulant therapy were identified as risk factors for SSI in noncolorectal abdominal surgery.⁹ However, others reported that operation time was the only statistically significant risk factor for SSI after gastrectomy,¹⁰ and in colorectal surgery, diabetes and a 10% weight loss were associated with SSI.¹¹ Among all of these studies, overweight was not identified as a risk factor for SSI. BMI exhibited a direct relationship with operation time in cholecystectomy, colectomy, and unilateral mastectomy, but it was not associated with surgical complications.¹² Thus, BMI may not directly influence the occurrence of surgical complications or SSI in abdominal surgery, but increased operation time and blood loss secondary to BMI may be responsible for any identified negative outcomes. However, we analyzed operation time and blood loss as intermediate factors instead of outcome variables, and BMI was still associated with the development of pancreatic fistula and abdominal abscess, as seen previously.⁸ This fact suggests that BMI has a direct effect on surgical complications besides indirect effects through operation time or blood loss.

Practically, the presence of a large amount of the viscera may disturb drainage of exudates and coag-

ula, and excess fatty tissue may become necrotic more easily as a result of surgical manipulation. In addition, the demarcation between pancreas and fat tissues in overweight individuals is obscure because of greater fat deposition in the pancreas.^{13,14} This could also be relevant in cases of gastrectomy requiring peripancreatic nodal dissection and mobilization of the pancreas. These factors may contribute to the increased occurrence of abdominal abscess and pancreatic fistula in overweight surgical patients.

Whites in general have a higher BMI than Japanese individuals, and the incidence of morbid obesity is marked and growing among patients in the United States and Europe. The proportions of patients with BMI \geq 25 and BMI > 30 in the present study were only 14.7% and 1.0%, respectively, whereas one-third of the U.S. population is obese (BMI > 27).¹⁵ These differences in patients' physique may partly explain observed differences in mortality and morbidity between the UK Medical Research Council (MRC) and Dutch trials and the present study.^{16,17} The mortality of patients undergoing D2 dissection in the two Western studies was 13% and 10%, whereas morbidity was 46% and 43%. In contrast, we observed only 1.3% mortality and 35.1% morbidity in overweight patients undergoing D2 or D3 dissection. In addition to possible differences in patients' physique, experience and workload volume of surgeons are important factors that could contribute to different surgical outcomes.

In patients undergoing D2, but not D3, dissection, overweight was associated with surgical complications. Although these differences were not statistically

significant, this may be because of low statistical power to test the interactions. In contrast, only the odds ratios of long operation time and excessive blood loss increased were statistically significant in the D3 dissection group, as reported previously.⁶ The increased risk of complications in nonoverweight patients in the D3 subgroup could explain these differences. Indeed, the cumulative incidence of all complications in normal patients was 17.8% in the D2 subgroup and 27.6% in the D3 subgroup. Thus, greater care should be taken in performing gastrectomy not only in all patients undergoing D3 dissection, but also in overweight patients undergoing D2 dissection.

The relationship between overweight and overall prognosis in patients with cancer is an important issue to resolve. The presence of excess fat impairs precise nodal dissection and decreases the yield of lymph nodes. In this study, the number of lymph nodes retrieved from overweight patients was far less compared with nonoverweight patients undergoing a D2, but not D3, dissection. In addition to the quality of lymph node dissection, comorbid conditions associated with overweight, such as cardiovascular diseases, pulmonary dysfunction, diabetes, and hypertension, may negatively affect the prognosis of postoperative patients.¹⁸ The relationship between overweight and overall survival in patients with gastric cancer remains controversial.¹⁻⁴ A conclusive result cannot be obtained without a well-controlled prospective study, and the final results of the JCOG9501 trial should answer this important question. However, the present study provides some insight into this issue.

The proportion of overweight patients in this trial was low (14.7%). Therefore, the obtained results are not definitely conclusive, but they clearly suggest that caution is needed when performing gastrectomy for gastric cancer in overweight patients. In conclusion, overweight increased the risk of surgical complications in patients undergoing gastrectomy with lymphadenectomy.

ACKNOWLEDGMENTS

Supported in part by Grant-in-Aid for Cancer Research from the Ministry of Health and Welfare and the Second Term Comprehensive 10-Year Strategy for Cancer Control by the Ministry of Health and Welfare, Japan. The authors thank Dr. Yoshimura for help with the statistical analysis, Ms. Hongo for data management, and Ms. Sugimoto for secretarial assistance. Participating institutions and

chief participants: National Cancer Center Hospital (M. Sasako, T. Sano), Niigata Cancer Center Hospital (A. Nashimoto, H. Yabuzaki), National Shikoku Cancer Centre (A. Kurita, Y. Kubo), Osaka Medical Center for Cancer and Cardiovascular Diseases (M. Hiratsuka, I. Miyashiro), Osaka National Hospital (K. Fujitani, M. Hirao), National Cancer Centre Hospital East (T. Kinoshita), Tokyo Metropolitan Komagome Hospital (K. Arai, Y. Iwasaki), Aichi Cancer Centre (T. Kito, Y. Yamamura), Osaka Medical College (K. Okajima, M. Tanigawa), International Medical Centre of Japan (O. Kobori, T. Shimizu), Sakai City Hospital, Kanagawa Cancer Centre (H. Furukawa, H. Imamura), Tokyo Metropolitan Bokuto Hospital (M. Kitamura, S. Inoue), Nagaoka Chuo General Hospital (T. Yoshikawa, T. Shimizu), Niigata City General Hospital (K. Aizawa), Cancer Institute Hospital (K. Ota, S. Oyama), Kyoto Second Red Cross Hospital (H. Tokuda, S. Takahashi), Saitama Cancer Centre, Hiroshima City Hospital (Y. Tanaka, K. Uchida), Kanazawa University (K. Miwa, T. Fujimura), Gifu Municipal Hospital (H. Tanemura, H. Oshita), Kagoshima University (T. Aiko, S. Hokita), Iwate Medical University (M. Terashima, K. Saito), and Okayama University (H. Isozaki).

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