

Supplementary Online Content

Yu J, Huang C-M, Su Y, et al. Effect of laparoscopic vs open distal gastrectomy on 3-year disease-free survival in patients with locally advanced gastric cancer: the CLASS-01 randomized clinical trial Yu J, Huang C-M, Sun Y, et al. *JAMA*. doi:10.1001/jama.2019.5359

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This supplementary material has been provided by the authors to give readers additional information about their work.

eTable 1. Eligibility Criteria for the Enrollment of the Patients

Inclusion
18 < age < 75 years
Primary gastric adenocarcinoma confirmed pathologically by endoscopic biopsy
cT2-4a, N0-3, M0 at preoperative evaluation according to the AJCC Cancer Staging 7th Edition
Expected curative resection via distal subtotal gastrectomy with D2 lymphadenectomy
Performance status of 0 or 1 on the ECOG (Eastern Cooperative Oncology Group) scale
ASA (American Society of Anesthesiology) score class I, II, or III
Written informed consent
Exclusion
Pregnant or breast-feeding women
Severe mental disorder
Previous upper abdominal surgery (except laparoscopic cholecystectomy)
Previous gastrectomy, endoscopic mucosal resection or endoscopic submucosal dissection
Enlarged or bulky regional lymph node diameter larger than 3 cm based on preoperative imaging
Other malignant disease within the past five years
Previous neoadjuvant chemotherapy or radiotherapy
Unstable angina, myocardial infarction, or cerebrovascular accident within the past six months
Continuous systematic administration of corticosteroids within one month prior to the study
Requirement of simultaneous surgery for other diseases
Emergency surgery due to a complication (bleeding, obstruction or perforation) caused by gastric cancer
FEV1 (Forced expiratory volume in 1 second) <50% of predicted values

eTable 2. Univariate and Multivariable Mixed Effects Cox Regression Analyses of Risk Factors for Survival

Variables	Disease-free survival				Overall survival			
	Univariate		Multivariable		Univariate		Multivariable	
	HR ^a (95% CI) ^b	P Value	HR (95% CI)	P Value	HR (95% CI)	P Value	HR (95% CI)	P Value
Procedure (laparoscopic vs open)	1.07 (0.83 to 1.39)	.59	1.10 (0.84 to 1.43)	.49	1.17 (0.86 to 1.59)	.33	1.19 (0.87 to 1.64)	.28
Age (≥60 vs <60 years)	1.58 (1.22 to 2.05)	<.001	1.52 (1.16 to 1.99)	.002	1.59 (1.16 to 2.17)	.004	1.53 (1.11 to 2.10)	.009
Sex (Male vs Female)	0.93 (0.71 to 1.22)	.58			0.91 (0.65 to 1.27)	.59		
Body-mass index (≥25 vs <25 kg/m ²) ^c	0.77 (0.55 to 1.08)	.13			0.78 (0.52 to 1.17)	.22		
ECOG score (1 vs 0)	1.01 (0.73 to 1.38)	.97			1.18 (0.81 to 1.72)	.40		
Comorbidity (Yes vs No)	1.00 (0.75 to 1.34)	.99			0.95 (0.67 to 1.36)	.78		
Tumor size (≥4.0 vs <4.0 cm)	2.40 (1.78 to 3.24)	<.001	1.18 (0.85 to 1.64)	.31	2.67 (1.83 to 3.89)	<.001	1.18 (0.74 to 1.76)	.43
Histology (signet-ring cell vs others)	0.94 (0.67 to 1.34)	.75			1.16 (0.77 to 1.73)	.47		
Pathological T stage ^d								
<T2	1 [Reference]		1 [Reference]		1 [Reference]		1 [Reference]	
T2-4a	4.42 (2.69 to 7.25)	<.001	1.80 (1.04 to 3.12)	.04	7.12 (3.33 to 15.22)	<.001	2.84 (1.26 to 6.41)	.01
T4b	22.29 (9.46 to 52.53)	<.001	7.39 (2.95 to 18.54)	<.001	54.62 (18.72 to 159.36)	<.001	17.16 (5.59 to 52.72)	<.001
Pathological N stage ^d								
N0	1 [Reference]		1 [Reference]		1 [Reference]		1 [Reference]	
N1	1.73 (1.03 to 2.88)	.04	1.27 (0.74 to 2.18)	.39	1.60 (0.81 to 3.18)	.18	1.18 (0.58 to 2.43)	.65
N2	3.03 (1.96 to 4.68)	<.001	2.39 (1.50 to 3.81)	<.001	3.37 (1.94 to 5.87)	<.001	2.62 (1.46 to 4.70)	.001
N3	7.61 (5.27 to 10.98)	<.001	5.24 (3.47 to 7.92)	<.001	8.83 (5.54 to 14.07)	<.001	5.74 (3.42 to 9.63)	<.001
Variables	Disease-free survival				Overall survival			
	Univariate		Multivariable		Univariate		Multivariable	
	HR^a (95% CI)^b	P Value	HR (95% CI)	P Value	HR (95% CI)	P Value	HR (95% CI)	P Value
Received adjuvant chemotherapy		<.001		.19		.23		
No	1 [Reference]		1 [Reference]		1 [Reference]			
Yes	1.61 (1.23 to 2.09)		1.21 (0.91 to 1.60)		1.22 (0.88 to 1.68)			

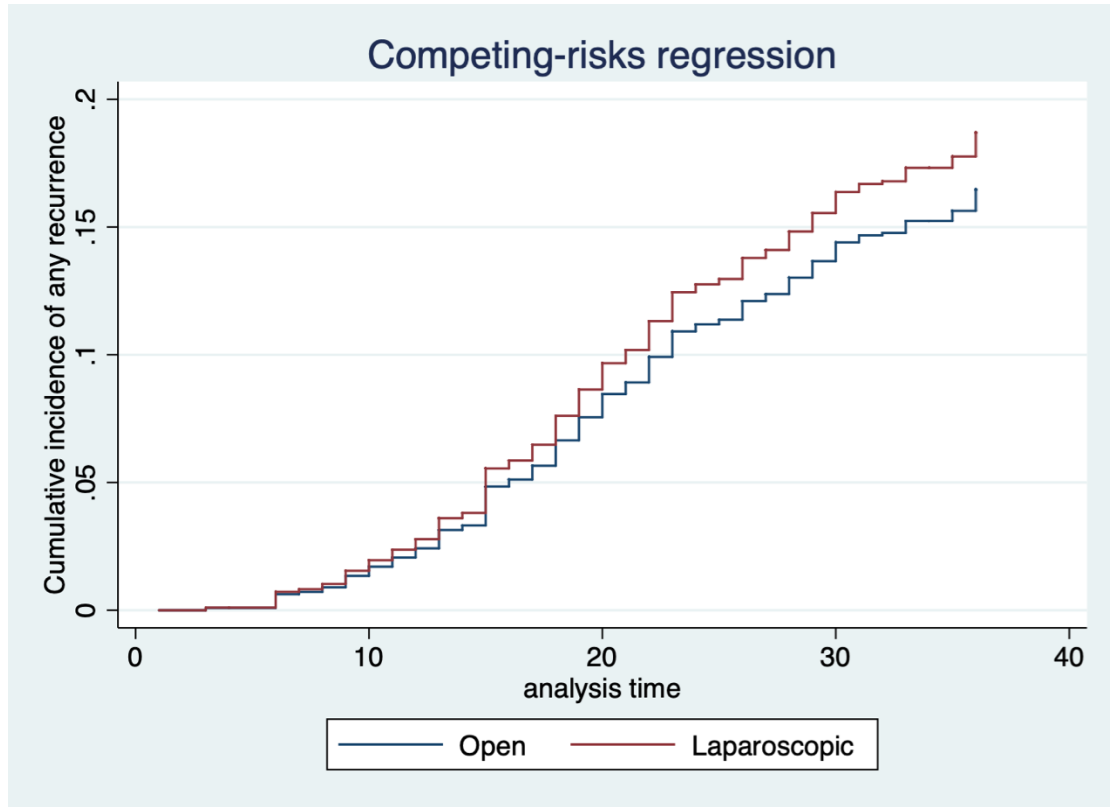
^aHR denotes hazard ratio for recurrence or death.

^bCI denotes confidence interval, estimated by mixed effects Cox proportional hazards model.

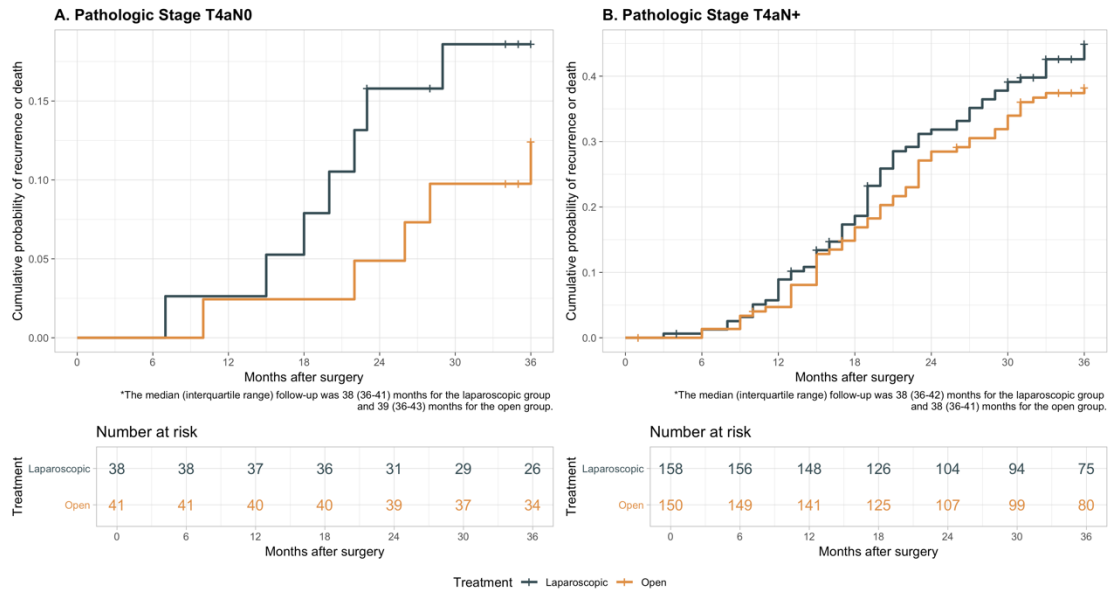
^cThe body-mass index is the body weight in kilograms divided by the square of the height in meters.

^dTumor stage according to American Joint Committee on Cancer 7th Edition.

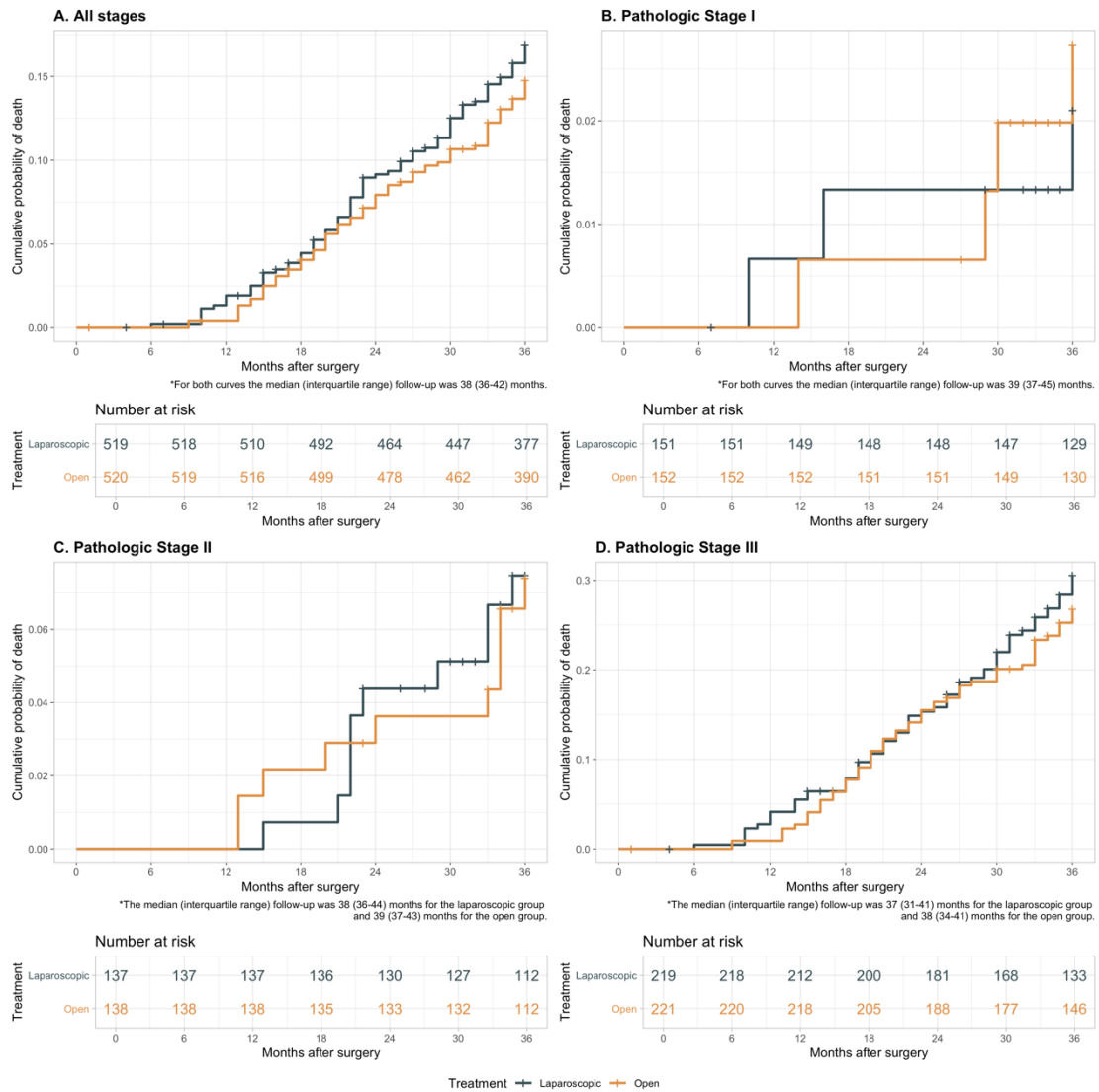
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