SPECIAL ARTICLE



Surgically treated gastric cancer in Japan: 2011 annual report of the national clinical database gastric cancer registry

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Abstract

Background The National Clinical Database (NCD) nationwide registry program of gastric cancer started in 2018. The purpose of this study was to report the treatment results of the NCD registry in the form of treatment results of the real world in Japan.

Methods Patients' characteristics, tumor features, treatments, and outcomes were collected using a web-based data entry system. We analyzed the initial NCD database for data on surgically treated gastric cancer patients in 2011.

Results A total of 30,257 patients with malignant gastric tumors were enrolled by the NCD registry program from 501 hospitals in all 47 prefectures. Of these, the status of data entry was not approved in 8.8% of the registered data, and follow-up information was missing in 1.2% of the approved cases. Excluding 1777 cases, which were not resected for primary gastric cancer, 25,306 resected cases included 44.4% of stomach surgeries recorded in the NCD. The 5 year survival rate of the resected cases was 71.3% and the operative mortality rate was 0.41%. The stage-specific 5 year survival rates were as follows: 89.6% for stage IA, 83.8% for stage IB, 77.3% for stage IIA, 69.1% for stage IIB, 58.7% for stage IIIA, 44.1% for stage IIIB, 30.1% for stage IIIC, and 13.4% for stage IV.

Conclusions The NCD gastric cancer registry program demonstrated validity for database construction. The gastric cancer registry is expected to become a nationwide registry with the dissemination of data entry system and method in the NCD.

Keywords Gastric cancer registry · National Clinical Database · Annual report

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Introduction

In 1963, the Japanese Research Society for Gastric Cancer launched a nationwide gastric cancer registry to collect details on the development and prevalence of the research on gastric cancer. This was the precursor of the Japanese Gastric Cancer Association (JGCA), and has been continued, with a decade of inactivity, to date by the JGCA [1–5]. A number of JGCA members voluntarily participate in this registry program. Surgical cases were registered in the JGCA first, and endoscopic cases were additionally registered from 2006. In 2018, 27,034 surgically treated patients were registered from 366 hospitals, and 8681 endoscopically treated patients were registered from 162 hospitals in the 2011 registry [1].

The National Clinical Database (NCD) of Japan was founded in April 2010 as a result of the participation of 10 surgical subspecialty academies associated with the board certification system [6, 7]. The NCD commenced data registration in 2011, and has since become a nationwide database covering more than 95% of the surgeries performed [8]. To date, more than 5200 facilities have enrolled in the NCD, with a registration of approximately 1,500,000 cases per year [9]. The NCD was built as a platform for surgical procedures to evaluating the practices and outcomes, and ultimately, provide better medical care. Additionally, some organ-specific cancer registries, such as those for pancreatic and breast cancer, were implemented to the NCD from the beginning, while hepatocellular cancer, urinary organ cancer, gastric cancer, and esophageal cancer were added later [10]. The Ministry of Health, Labour and Welfare has planned to construct databases of organ-specific cancer registries for patterns of care study and selected NCD as an organization of gastric cancer registry in 2017 [5]. In such a situation, the registration committee of the JGCA and NCD planned to apply the same registration items of the conventional JGCA gastric cancer registry to the NCD gastric cancer registry, which started in 2018. Concomitantly, the registration method was changed from a by-mail to a web-based entry system.

Because data registration in the NCD program that can collect more nationwide data than the conventional program has started, we herein report that gastric cancer registry has led to a better understanding of the real-world situation with respect to gastric cancer in Japan.

Methods

Data source

The registered gastric malignant tumors were primary gastric cancer, remnant gastric cancer, gastrointestinal stromal tumor, malignant lymphoma, and other malignant tumor, and were all treated in 2011. The registration data are listed in Table 1, and consist of the same 73 items as the JGCA registry program, including personal information, surgical results, histological diagnosis, final diagnosis, treatment, and follow-up information according to the Japanese Gastric Cancer Association classification (14th edition), UICC TNM classification (7th edition), and the Japanese gastric cancer treatment guidelines (2010) [11–13]. The data were registered in the NCD using a web-based data entry system, by uploading an exported data set registered in the JGCA program, by direct data entry as a result of a relationship with previously registered surgeries, or by direct data entry in an organ-specific cancer registry site. The NCD gastric cancer registration program was approved by the Institutional Review Board of the Graduate School of Medicine, Kobe University (No.180265).

Table 1	Registration	data
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Category	Item
Personal information	Name of hospital, date of birth, age at operation
Surgical results	Date of operation, approach, procedure, lymph node dissection, combined organ resection, type of reconstruction
Histological diagnosis	Tumor location, size, histological type, depth of tumor invasion, capillary invasion (ly, v), number of resected lymph node, number of metastatic lymph node, resection margin (PM, DM), CY
Final diagnosis	Macroscopic type, depth of invasion, fN, H, P, M, residual tumor, stage
Treatment	Chemotherapy (preoperative, intraoperative, postoperative), immunotherapy, radiotherapy
Follow-up information	Date of follow-up, life and death, cause of death, site of recurrence

PM proximal margin, DM distal margin, CY peritoneal lavage cytology, f final findings,

N lymph node metastasis, H hepatic metastasis, P peritoneal metastasis, M distant metastasis

Statistical analysis

The collected data of primary gastric cancer patients were analyzed for 5 year survival rate considering various subgroups of prognostic factors, including patient characteristics, tumor status, and surgical procedure. The following data were calculated: total patients; direct death within 30 postoperative days; patients lost to follow-up within 5 years; survival rates by year; standard error of 5 year survival; 5 year survivors; death from gastric cancer, other cancer, other disease, and unknown cause; and recurrence site, such as local, lymph node metastasis, peritoneal metastasis, liver metastasis, and unknown site. The overall survival rates were calculated using the Kaplan–Meier method and were compared using the log-rank test. *P* values of < 0.05 were considered statistically significant. All statistical analyses were performed using SPSS Statistics 25.0 (IBM, USA).

Results

The data of 30,257 patients with malignant gastric tumors were enrolled from 501 hospitals in all 47 prefectures. The geographical distribution of the participating hospitals is illustrated in Fig. 1a. The median number of hospitals per prefecture was 7 (range 2–48). The composition of the enrolled data is shown in Fig. 1b. High-volume centers, recording more than 100 cases per year, accounted for 16.2% of all participating hospitals. Of 30,257 cases, 2656 cases (8.8%) without data entry approval and 325 cases (1.2%) without follow-up information were excluded. Additionally, 654 cases, including cases of remnant gastric cancer or other malignant tumor, cases with synchronous malignancy, nonsurgical cases, and palliative surgery cases, were excluded. The remaining 26,622 patients were used for the analyses.

The 5 year survival rate (5YSR) of all patients with primary gastric cancer was 68.4% (Fig. 2a). With the exclusion of 1123 unresected cases, 189 atypically surgical procedure cases, and 4 unknown cases, the 5YSR was 71.3%, and the 30 day operative mortality rate was 0.41% in the 25,306 resected cases (Fig. 2b). Analyses of various subgroups for patient demographics and gastric cancer characteristics were performed for resected cases (Table 2). Patients aged \geq 80 years old comprised 15.6% of the population, and their 5YSR was 49.6%, whereas that of patients aged 40–59 years old was 82.9% (P < 0.001) (Fig. 2c). The proportion of male patients was 68.9%, and their 5YSR was lower than that of female patients (69.1% vs. 74.8%, P < 0.001) (Fig. 2d). With regards to the primary tumor, tumors in the upper-third of the stomach with esophageal invasion accounted for 23.4%, and the 5YSR (63.3%) of these cases was lower than the cases with tumors located at the middle-third (76.6%) and lower-third and duodenum (70.3%) (*P* < 0.001) (Fig. 2e). The 5YSR of type 4 tumor was remarkably low at 25.2%, and the 28.3% of this tumor had peritoneal recurrence (Fig. 2f). With regards to histological classification, the proportion of undifferentiated tumor types, including poorly differentiated adenocarcinoma, signet-ring cell carcinoma, and mucinous adenocarcinoma was 45.9%, and their 5YSR was lower than that of differentiated type tumors, such as papillary adenocarcinoma and tubular adenocarcinoma (66.8% vs. 74.4%, *P* < 0.001) (Fig. 2g). Early gastric cancer (pT1) accounted for 48.2%, the 5YSR was 88.7%, and death from gastric cancer was only 0.25% (Fig. 2h, i). Progression of venous invasion and lymphatic invasion were associated with poor prognosis (Fig. 2j, k). The proportion of cases that were negative for lymph node metastasis was 59.8%, and their 5YSR was 85.5% (Fig. 21). In cases with non-curative factors, the presence of distant metastasis, peritoneal metastasis, positive peritoneal lavage cytology, and liver metastasis showed similar 5YSRs (Fig. 2m-p). The 5YSRs of patients stratified by pathological stage were 89.6% for stage IA, 83.8% for stage IB, 77.3% for stage IIA, 69.1% for stage IIB, 58.7% for stage IIIA, 44.1% for stage IIIB, 30.1% for stage IIIC, and 13.4% for stage IV (Fig. 2q, r). The results for surgical procedure and outcome are shown in Table 3. The groups classified based on surgical procedure had various tumor characteristics and survival differences among procedure groups were not precisely evaluated. Laparoscopic surgery was performed in 31.1%. Thoraco-laparotomy, which was performed for tumors with esophageal invasion, accounted for only 0.6%. Distal gastrectomy accounted for 59.6% and total gastrectomy was performed in 32.9%. D2 lymph node dissection was carried out for 43.6% of all resected patients, and had a low incidence of direct death at 0.25%. Combined resection was performed in 31.5% of all cases. R0 resection was achieved for 89.9%, and the 5YSR was 77.0% (Fig. 3). The predominant site of recurrence after R0 resection was the peritoneum, followed by the liver and distant lymph nodes.

Discussion

The initial NCD gastric cancer registry collected 30,257 surgically treated cases from 501 hospitals in all 47 prefectures. The 55,278 stomach cancer surgeries, including total gastrectomy, distal gastrectomy, proximal gastrectomy,

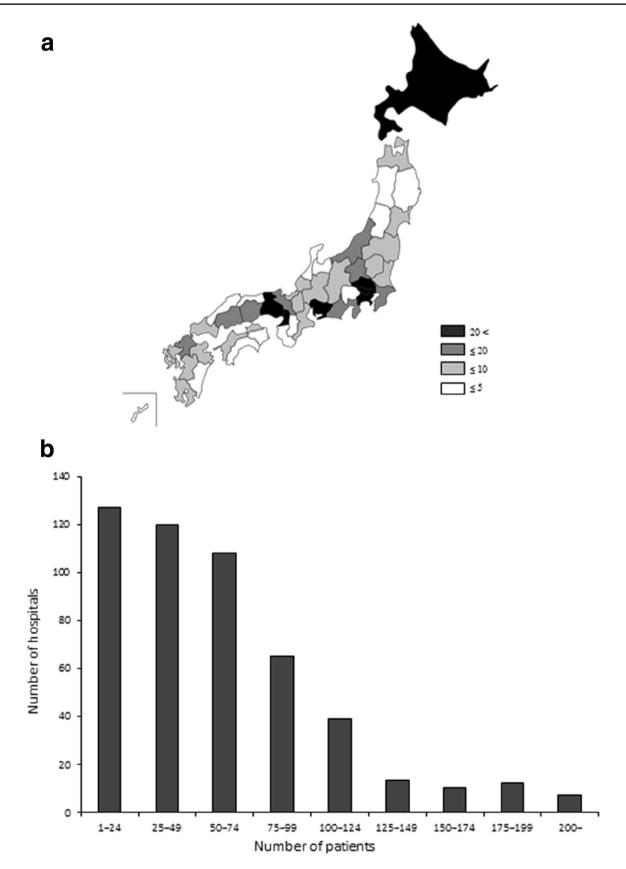


Fig. 1 a Geographic distribution of the registered hospitals in 47 prefectures. b Patient volume in the participating hospital

Table 2 Gast	Table 2 Gastric cancer characteristics						
Category	Total Direct death	Lost Postoperative survival rate (%)	l rate (%) S.E Site of recurrence			Alive Cause of death	
	number	f.u <u>1 yr 2 yr 3 yr</u>	4 yr 5 yr at L LN 5 yr	۵.	H R	PD OC	OD UK
Primary cancer	26,622 164	3316 88.0 80.675.2	71.468.4 0.3 232 530	1447	907 46	13,835 1585 498	1317 675
Resected case	Resected cases and unresected cases						
Resected	25,306 104 3184	91.283.678.2	74.371.3 0.3199 501	1261	872 39	872 39 13,746 994	479 1265 630
Unresected	1123 50 105	39.3 17.49.1	6.4 5.1 0.8 29 23	177	28 6	39 540	12 38 39
Other cases	189 10 26	63.948.442.9	39.335.0 3.9 4 6	6	7 1	48 51	7 14 6
Age (resected cases)	d cases)						
-39	444 0 52	96.3 89.8 85.2	82.880.9 2.0 3 6	37	9 0	289 12	4 3 1
40–59	4124 4 427	96.091.086.9	84.882.9 0.6 24 69	210	101 5	2729 102	26 49 31
6079	16,140 66 1762	91.784.479.0	75.072.0 0.4 119 335	818	615 20	9108 618	331 735 342
80-	3830 30 792	81.768.961.3	54.949.6 0.9 49 85	188	141 13	1152 253	103 456 241
Sex (resected cases)	l cases)						
Male	16,923 78 2054	90.582.576.6	72.3 69.1 0.4 143 372	781	687 24	8921 677	393 979 445
Female	7622 22 980	92.185.080.8	77.474.8 0.5 53 123	473	179 14	4361 308	71 264 170
Tumor locati	Tumor location (resected cases)						
Upper third esopha- geal inva-	l 5712 26 648 -	88.478.771.9	67.163.3 0.7 54 144	325	288 16	2786 318	117 379 163
sion							
Middle third 9749	d 9749 25 1196	93.187.182.6	79.276.6 0.5 49 134	434	273 9	5739 271	179 420 199
Lower third duodenum	l 8824 46 1154 n	90.8 82.8 77.4	73.370.3 0.5 87 206	448	293 9	4690 365	164 424 245
Whole	170 2 20	66.946.931.0	28.125.8 3.7 68	43	9 4	33 24	2 8 6
Macroscopic	Macroscopic type (resected cases)						
Type 0	12,497 22 1594	97.7 95.4 92.9	90.588.1 0.3 23 34	56	100 3	8614 57	263 542 199
Type 1	908 10 153	87.877.670.2	64.861.2 1.8 3 21	27	47 3	385 35	28 89 40
Type 2	3960 23 494	88.778.071.0	65.861.9 0.8 38 132	175	279 4	1829 196	68 253 132
Type 3	4646 31 508	83.7 69.1 60.1	54.3 50.5 0.8 71 214	476	330 16	1758 382	75 234 159
Type 4	1564 9 153	69.448.436.7	28.9 25.2 1.2 44 54	442	61 9	287 250	18 62 47
Type 5	778 3 92	83.671.361.4	56.052.4 1.9 16 32	74	47 3	310 53	9 54 36
Histological	Histological finding (resected cases)						
Differenti-	12,847 54 1691	93.587.182.0	77.774.4 0.4 73 202	302	476 15	7268 331	300 755 349
ated type							

549

	(non III)								
Category	Total	Direct death	Lost Postoperative survival rate (%)	al rate (%) S.E Site of recurrence			Alive Cause of death		
	number		f.u 1 yr 2 yr 3 yr	4 yr 5 yr at L LN 5 yr	d	HR	PD OC	QO	D UK
Undifferenti-11,268 43 1287 ated type	i-11,268	43 1287	88.379.173.3	70.066.8 0.5119 287	947	357 23	5808 631	155 4	155 469 256
Other type	430	3 56	87.477.473.5	70.7 68.8 2.5 4 6	S	33 0	206 23	6	19 10
Histological type (resected cases)	type (rese	scted cases)							
pap	656	6 110	89.479.172.0	67.1 63.9 2.1 4 17	11	45 1	294 24	18	54 23
tub1	5178	15 735	96.191.887.6	83.981.0 0.6 14 46	57	89 4	3144 77	127 3	302 116
tub2	7013	33 846	91.984.578.8	74.270.6 0.6 55 139	234	342 10	3830 230	155 3	399 210
porl	3191	15 398	87.378.273.1	69.4 66.7 0.9 30 112	152	145 2	1613 175	46 1	175 78
por2	5057	22 528	86.174.667.3	63.1 59.7 0.7 63 131	636	169 13	2334 355	68 2	201 127
sig	2501	5 300	94.3 90.5 87.8	85.483.3 0.8 19 16	100	25 4	1635 62	35	66 38
muc	519	1 61	87.473.363.0	58.256.0 2.3 7 28	59	18 4	226 39	9	27 13
Endocrine	94	0 13	80.9 62.0 56.4	50.548.9 6.0 2 3	1	16 0	30 7	2	4
cell carci- noma									
Carcinoma with lymphoid	89	2 11	91.985.984.7	82.282.2 4.2 0 0	0	0 0	60 2	1	9 3
stroma									
Hepatoid adenocar- cinoma	27	0 6	76.2 64.9 58.1	58.158.111.6 0 0	1	5 0	8 1	1	0 0
Adenos- quamous	19	0 0	58.847.135.3	35.3 29.4 11.1 0 1	1	3 0	5 4	0	3 0
carcinoma	-								
Squamous cell carci- noma	14	0 2	100 91.791.7	91.782.511.3 01	0	0 0	9 1	0	0 0
Undiffer- entiated carcinoma	20	0 1	89.578.667.4	61.861.811.4 0 1	6	3 0	11 1	0	0 0
Miscel- laneous carcinoma	167 1	1 23	92.3 85.2 82.7	81.078.2 3.7 2 0	0	6 0	83 7	Ś	3 4
Tumor invasion (resected cases)	on (resec	ted cases)							
pT0	101	0 12	100 95.791.3	85.684.4 3.8 0 3	5	2 0	71 2	0	1
pT1a(M)	5341	8 735	98.2 96.6 94.9	0.4 4	4		3766 10	95 2	201 78
pT1b(SM)	6463	10 817	076050007	30 2 06 7 0 5 1 75	15		10001	011	101 000

Table 2 (continued)	ntinued)							
Category	Total Direct death	Lost Postoperative survival rate (%)	ival rate (%) S.E Site of recurrence			Alive Cause of death	h	
	number	f.u 1 yr 2 yr 3 yr	4 yr 5 yr at L LN 5 yr	ď	H R	PD OC	00	UK
pT2(MP)	2746 14 360	95.590.385.2	81.678.2 0.9 15 49	19	91 2	1639 34	54 168	76
pT3(SS)	4347 18 509	89.679.671.7	65.9 62.0 0.8 53 154	234	312 8	2066 193	98 248 1	119
pT4a(SE)	4775 36 515	76.056.745.9	39.235.1 0.8 92 229	848	330 22	1210 588	58 240 1	184
pT4b(SI)	694 12 70	63.2 39.8 30.3	24.821.5 1.7 26 29	129	50 2	106 134	7 48	35
Subclassifics	Subclassification of submucosa (resected cases)	ted cases)						
SM1	1662 3 224	97.696.093.1	90.187.0 0.9 1 2	4	11 1	1133 5	41 87	35
SM2	4815 8 595	97.694.691.7	89.086.5 0.5 3 21	12	68 3	3269 16	106 246	87
Lymphatic ir	Lymphatic invasion (ly) (resected cases)	s)						
ly0	11,053 21 1459	97.194.3	91.188.586.1 0.427 48		155 98 3	7439 93	207 485 2	216
ly1	6225 29 752	92.7 85.2	79.474.771.1 0.656 99	-	282 227 11	3377 207	137 355 1	154
ly2	3787 12 422	84.471.3	62.556.953.1 0.958 146	91	359 267 7	1508 256	68 225 1	126
ly3	3217 35 353	73.554.1	45.039.335.9 0.952 197	7	448 269 17	823 417	47 164 1	116
Venous inva	Venous invasion (v) (resected cases)							
v0	13,340 30 1749	96.3 92.7 89.2	86.283.6 0.3 49 106	296	159 5	8641 142	251 608 2	275
v1	5959 22 677	88.177.671.0	66.2 62.5 0.7 69 178	458	266 20	2841 323	125 325 1	154
v2	3371 24 397	82.267.758.2	52.549.0 0.9 51 139	329	242 11	1221 295	58 198 1	129
v3	1609 21 159	74.455.546.9	41.438.0 1.3 24 65	161	196 2	451 211	26 99	53
Lymph node	Lymph node metastasis (resected cases)	s)						
pN0	14,560 31 1948	97.094.191.1	88.1 85.5 0.3 39 51	191	111 6	9614 106	308 726 2	276
pN1	3265 10 408	92.184.278.1	73.570.2 0.9 36 49	147	147 4	1737 126	58 170	89
pN2	2724 17 297	84.870.962.3	56.853.0 1.0 46 106	221	228 10	1091 183	46 159	94
pN3a	2306 15 209	77.557.445.1	38.434.2 1.1 49 160	345	230 9	600 281	28 104	90
pN3b	1509 17 140	64.5 39.5 27.9	21.117.8 1.1 22 125	339	145 9	193 258	18 67	59
Distant meta	Distant metastasis (M) (resected cases)							
fM0	22,292 69 2828	94.188.083.1	79.276.1 0.3154 390	787	682 29	13,040 405	443 1143 5	531
fM1	247 30 177	57.932.821.8	15.8 13.4 0.8 40 103	461	181 9	200 576	19 90	83
Peritoneal m	Peritoneal metastasis (P) (resected cases)	es)						
fP0	23,262 80 2893	92.3 86.080.9	76.973.8 0.3 172 464	971	798 31	13,171 596	449 1186 5	573
fP1	1153 18 118	54.1 28.2 17.2	12.0 9.3 1.0 21 28	274	63 6	69 377	12 46	38
Peritioneal c	Peritioneal cytology (CY) (resected cases)	ses)						
CYO	11,713 40 1309	91.3 82.175.5	70.8 67.3 0.5 118 339	687	579 20	6142 391	211 644 3	334
CY1	1335 17 115	58.232.021.3	15.012.1 1.0 20 56	346	98 7	113 335	8 62	53
Liver metast	Liver metastasis (H) (resected cases)							
0HJ	24,054 87 2980	91.784.278.8	74.871.8 0.3 188 489	1222	799 38	13,213 833	455 1215 5	598
								1

Table 2 (continued)	ntinued)								
Category	Total	Total Direct death	Lost Postoperative survival rate (%)	ıl rate (%)	S.E Site of recurrence			Alive Cause of death	
	number		f.u <u>1</u> yr 2 yr 3 yr	$\frac{4 \text{ yr } 5}{5 \text{ yr at }}$	at L LN 5 vr	Ь	H R	PD OC	OD UK
fH1	372	372 12 32	46.425.318.2	14.7 13.5 2.0	2.0 5 4	19	63 0	34 136	4 17 15
Stage (resected cases)	ed cases)								
Stage IA	10,457	10,457 16 1397	98.196.394.1	91.989.6 0.3	0.3 3 10	8	30 3	7288 16	222 463 173
Stage IB	2501	2501 5 334	97.293.890.0	86.883.8 0.8	0.8 10 16	12	44 1	1599 10	50 142 57
Stage IIA	2294	7 278	95.390.486.3	81.677.3	0.9 16 23	48	74 1	1391 25	56 144 60
Stage IIB	1994	1994 10 258	92.984.677.2	72.3 69.1	1.1 25 50	116	87 3	1051 47	32 118 52
Stage IIIA	1667	1667 7 181	90.878.269.0	63.058.7 1.3	1.3 28 55	103	135 5	743 65	33 95 61
Stage IIIB	1650	1650 9 176	84.3 68.056.6	48.644.1	1.3 28 109	202	165 8	547 89	29 98 57
Stage IIIC	1533	1533 9 171	76.754.441.8	34.930.1	1.3 40 119	291	143 8	335 136	18 71 67
Stage IV	2167	2167 30 181	57.8 32.821.7	15.813.4 0.8	0.8 40 103	465	181 9	201 583	19 92 83
Stage (4 clas	sification)	Stage (4 classification) (resected cases)	(
Stage I	12,958	12,958 21 1731	97.995.893.3	90.988.5 0.3	0.3 13 26	20	74 4	8887 26	272 605 230
Stage II	4288	4288 17 536	94.287.782.1	77.3 73.5	0.7 41 73	164	161 4	2442 72	88 262 112
Stage III	4850	4850 25 528	84.167.356.3	49.3 44.8	0.8 96 283	596	443 21	1625 290	80 264 185
Stage IV	2167	30 181	57.832.821.7	15.8 13.4	0.8 40 103	465	181 9	201 583	19 92 83
Unknown ca	ses were e	sxcluded. NX, M	Unknown cases were excluded. NX, MX, PX, CYX, HX, RX were excluded	excluded					

ease, OC other cancer, OD other disease, UK unknown, Pap papillary adenocarcinoma, tubI tubular adenocarcinoma, well differentiated type, tub2 tubular adenocarcinoma, moderately differentiated type, porly differentiated adenocarcinoma, moderately differentiated type, porly differentiated type, porly differentiated adenocarcinoma, monesolid type, sig signet-ring cell carcinoma, muc mucinous adenocarcinoma, p pathological findings, T0 no evidence of tumor, M mucosa or muscuralis mucosa, SM submucosa, MP muscularis propria, SS subserosal, SE serosa, SI adjacent structure, f final findings Direct death direct death within 30 postoperative days, Lost f.u. lost to follow-up, SE standard error, L local, LN lymph node, P peritoneum, H liver, R recurrence at known site, PD primary dis-

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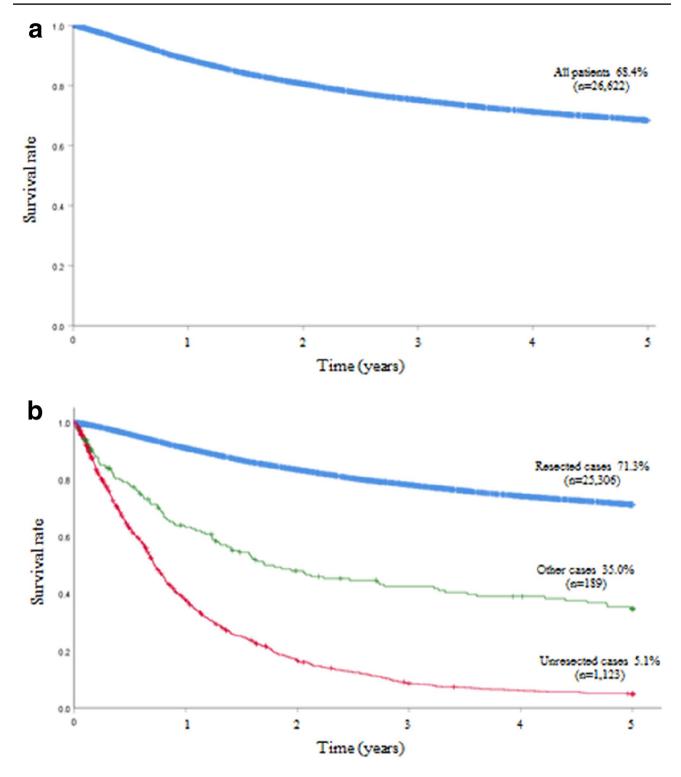


Fig. 2 Kaplan–Meier survival curves of patients stratified to various subsets of prognostic factors for patient demographics and tumor characteristics. **a** All patients with primary gastric cancer, **b** resected cases and unresected cases, **c** age category, **d** sex, **e** tumor location, **f** macroscopic type, **g** histological classification, **h** depth of tumor inva-

sion, **i** depth of subclassification of submucosa, **j** lymphatic invasion, **k** venous invasion, **l** lymph node metastasis, **m** distant metastasis, **n** peritoneal metastasis, **o** peritoneal cytology, **p** liver metastasis, **q** stage, and **r** stage (IV classification)

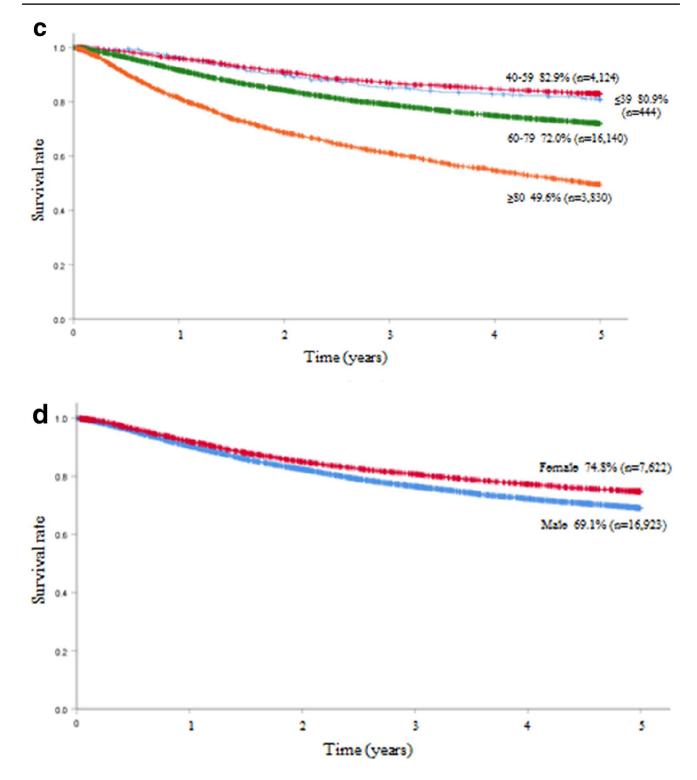


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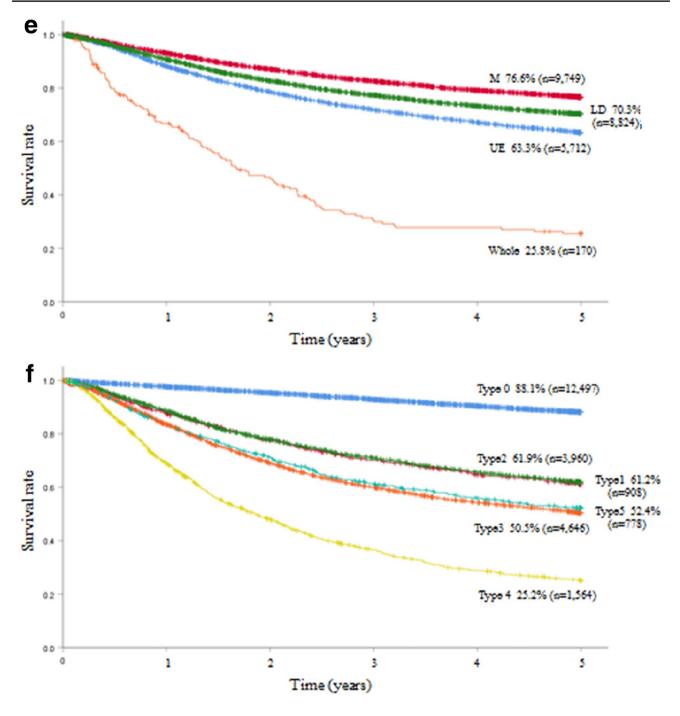


Fig. 2 (continued)

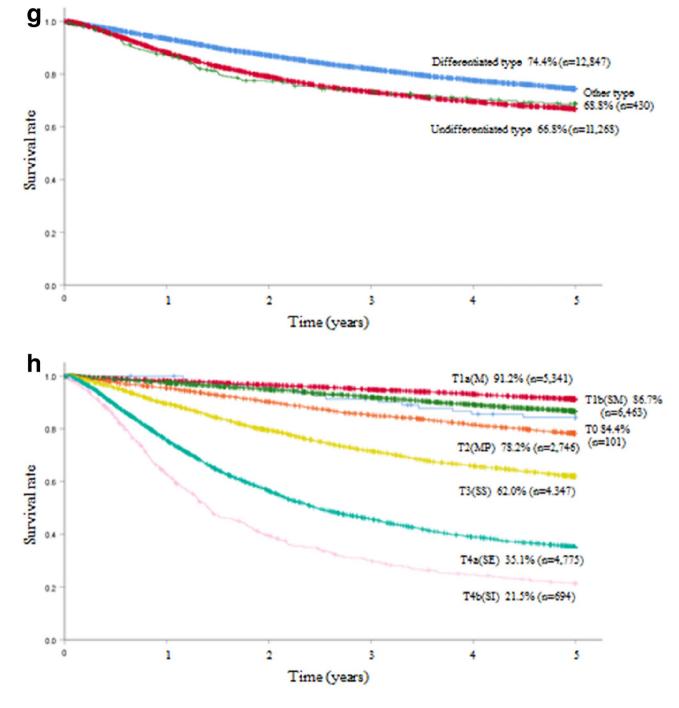


Fig. 2 (continued)

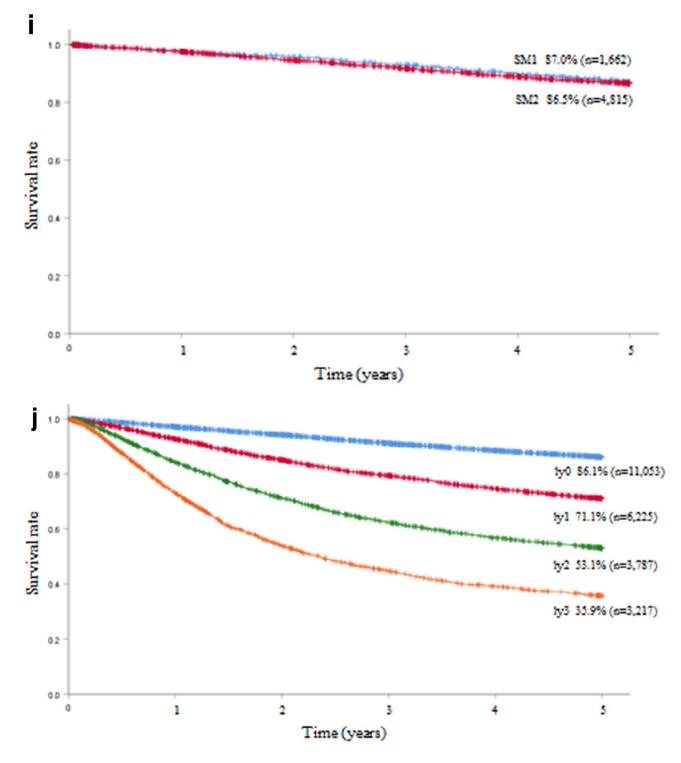


Fig. 2 (continued)

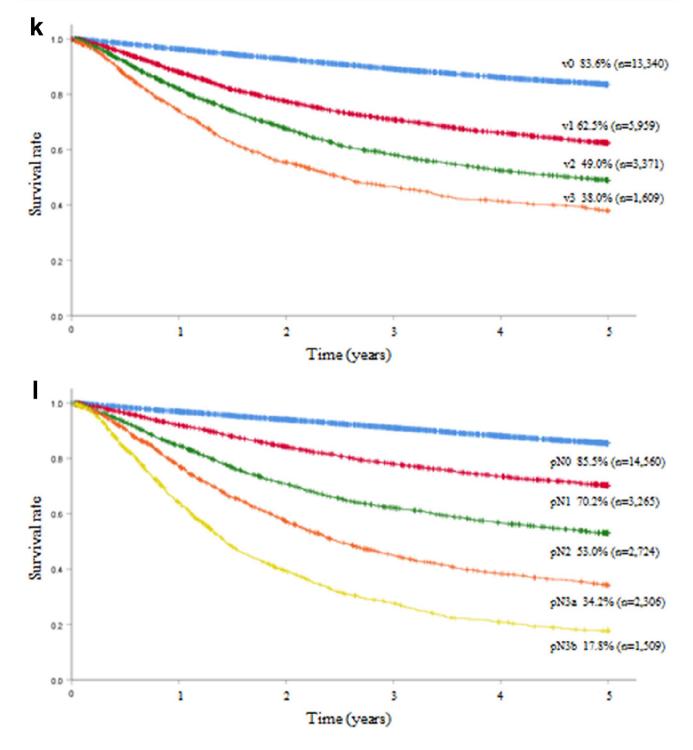


Fig. 2 (continued)

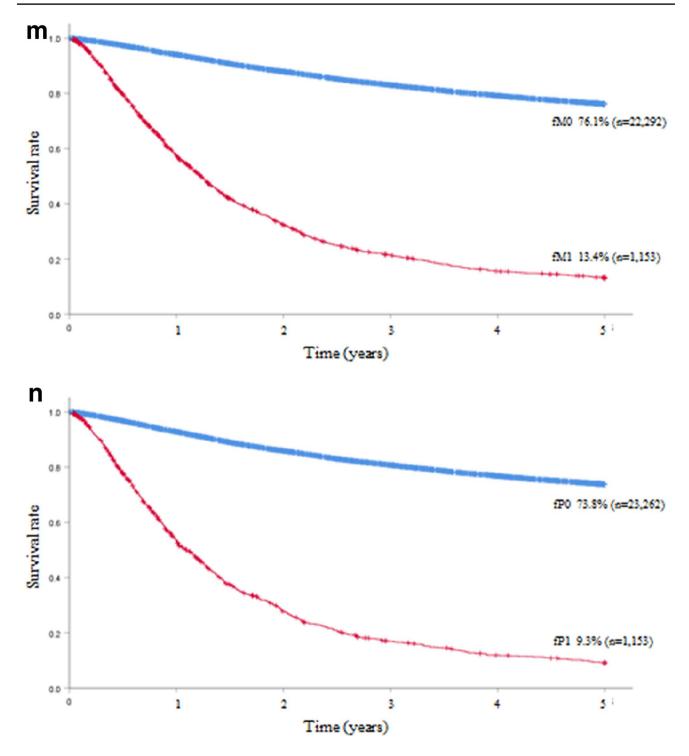


Fig. 2 (continued)

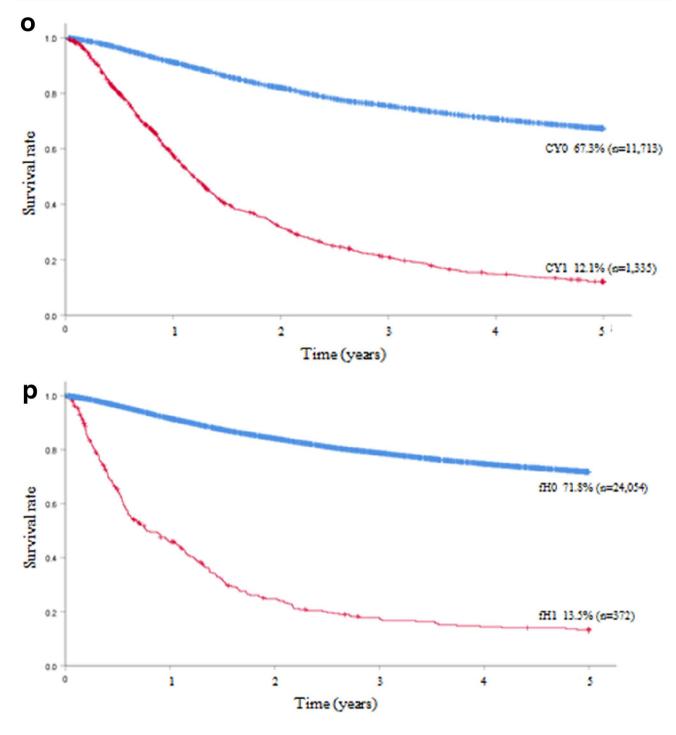


Fig. 2 (continued)

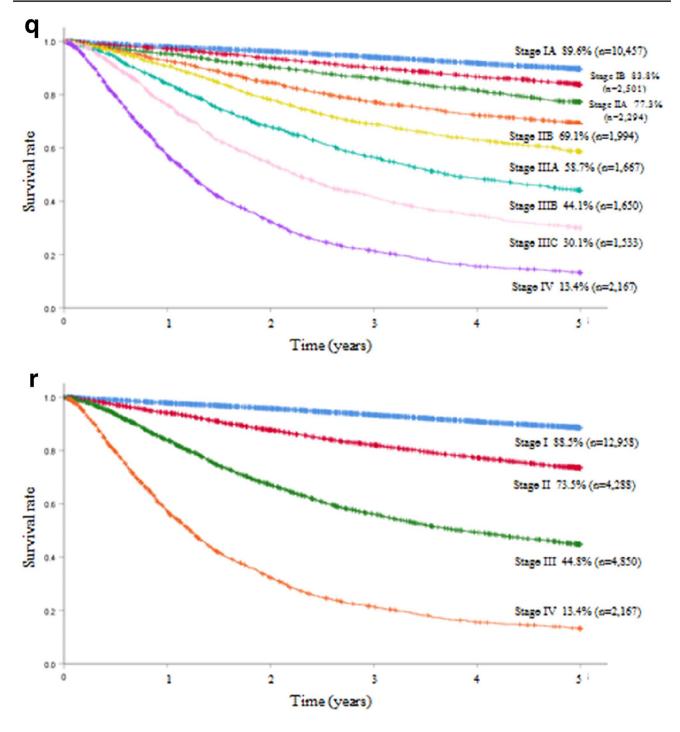


Fig. 2 (continued)

pperative survival rate (%) S.E Site of red 2 yr 3 yr 4 yr 5 yr $a_1 5$ yr L 77.8 71.2 66.4 63.0 0.4 176 64.4 46.2 42.9 38.4 4.3 6 95.4 92.6 90.3 88.1 0.4 176 79.1 79.1 74.6 72.1 6.6 0 79.1 79.1 74.6 72.1 6.6 0 79.1 79.1 74.6 72.1 6.6 0 79.1 79.1 74.6 72.1 6.6 0 87.4 83.1 79.5 76.8 0.4 105 87.4 83.1 79.6 0.6 0.6 0 88.0 88.1 0.76 0.6 0.6 0.6 88.1 74.9 76.0 0.6 0.8 0.6	pperative survival 2 yr 3 yr 77.8 71.5 64.4 46.5 95.4 92.6 79.1 79.1 79.1 79.1 79.1 79.1 79.1 79.1 87.4 83.1 89.0 84.5 99.5 98.2 86.0 78.1	ate (1			ite of rec	currence LN P	μ		Alive	Cause	Cause of death		
r $2yr$ $3yr$ $4yr$ $5yr$ $af 5yr$ L 0 77.8 71.2 66.4 63.0 0.4 176 8 64.4 46.2 42.9 38.4 4.3 6 7 95.4 92.6 90.3 88.1 0.4 14 4 79.1 79.1 74.6 72.1 6.6 0 4 79.1 79.5 76.8 0.4 105 0 3 73.6 65.9 60.7 56.9 0.6 0 3 89.0 84.5 81.0 78.2 1.5 5 3 89.0 84.5 81.0 78.2 1.5 5 3 89.5 98.3 97.6 96.6 0.8 1 5 88.3 97.6 96.6 0.8 1 6 65.9 66.6 96.6	2 yr 77.8 95.4 79.1 87.4 89.0 89.0 89.0									6			
0 77.8 71.2 66.4 63.0 0.4 176 8 64.4 46.2 42.9 38.4 4.3 6 7 95.4 46.2 42.9 38.1 0.4 14 7 95.4 92.6 90.3 88.1 0.4 14 4 79.1 79.1 74.6 72.1 6.6 0 5 87.4 83.1 79.5 76.8 0.4 105 3 73.6 65.9 60.7 56.9 0.6 84 3 89.0 84.5 81.0 78.2 1.5 5 5 86.0 78.1 74.9 70.0 3.0 1 5 86.0 78.1 74.9 70.0 3.0 1 5 86.0 53.3 83.3 15.2 0 3 83.3 83.3 33.3 15.2 0 6 69.0 64.9 61.	77.8 64.4 95.4 87.4 89.0 89.5 99.5		63.0 38.4					R		П	OC	OD	UK
8 64.4 46.2 42.9 38.4 4.3 6 7 95.4 92.6 90.3 88.1 0.4 14 4 79.1 79.1 74.6 72.1 6.6 0 5 87.4 83.1 79.5 76.8 0.4 105 2 3 73.6 65.9 60.7 56.9 0.6 84 2 3 89.0 84.5 81.0 78.2 1.5 5 3 89.0 84.5 81.0 78.2 1.5 5 3 89.0 84.5 81.0 78.2 1.5 5 3 89.0 84.5 81.0 78.2 1.5 5 3 89.0 84.5 90.6 0.8 1 1 5 90.5 98.3 83.3 15.2 0 1 5 86.0 78.3 83.3 15.2 0 0 6 74.2 69.0 64.9 61.2 0.9 22 0	64.4 95.4 79.1 87.4 89.0 89.0 86.0		38.4			447 1	1137 765	35	7978	927	334	950	506
7 95.4 92.6 90.3 88.1 0.4 14 4 79.1 79.1 74.6 72.1 6.6 0 5 87.4 83.1 79.5 76.8 0.4 105 2 3 73.6 65.9 60.7 56.9 0.6 84 2 3 89.0 84.5 81.0 78.2 1.5 5 3 89.0 84.5 81.0 78.2 1.5 5 8 99.5 98.3 97.6 96.6 0.8 1 8 99.5 98.3 97.6 96.6 0.8 1 8 99.5 98.3 83.3 15.2 0 3 83.3 83.3 15.2 0 3 60.0 53.7 50.3 47.0 1.8 18 6 74.2 69.0 64.9 61.2 0.9 22 0 90.4 86.7 83.6 81.3 0.5 44 14 <td>95.4 79.1 87.4 89.0 99.5 86.0</td> <td></td> <td></td> <td>4.3</td> <td>9</td> <td>15</td> <td>12 17</td> <td>0</td> <td>41</td> <td>12</td> <td>6</td> <td>×</td> <td>9</td>	95.4 79.1 87.4 89.0 99.5 86.0			4.3	9	15	12 17	0	41	12	6	×	9
	79.1 87.4 89.0 99.5 86.0		88.1		14	29	102 82	б	5236	46	124	282	102
5 87.4 83.1 79.5 76.8 0.4 105 3 73.6 65.9 60.7 56.9 0.6 84 3 89.0 84.5 81.0 78.2 1.5 5 3 89.0 84.5 81.0 78.2 1.5 5 8 99.5 98.3 97.6 96.6 0.8 1 5 86.0 78.1 74.9 70.0 3.0 1 5 86.0 78.1 74.9 70.0 3.0 1 3 83.3 83.3 83.3 15.2 0 0 3 60.0 53.7 50.3 47.0 1.8 18 6 74.2 69.0 64.9 61.2 0.9 22 90.4 86.7 83.6 81.3 0.5 44	87.4 73.6 89.0 86.0		72.1	9.9	0	4	3 2	0	27	0	0	б	1
5 87.4 83.1 79.5 76.8 0.4 105 3 73.6 65.9 60.7 56.9 0.6 84 3 89.0 84.5 81.0 78.2 1.5 5 8 99.5 98.3 97.6 96.6 0.8 1 8 99.5 98.3 97.6 96.6 0.8 1 5 86.0 78.1 74.9 70.0 3.0 1 3 83.3 83.3 83.3 15.2 0 3 60.0 53.7 50.3 47.0 1.8 18 6 74.2 69.0 64.9 61.2 0.9 22 90.4 86.7 83.6 81.3 0.5 44	87.4 73.6 89.0 86.0												
3 73.6 65.9 60.7 56.9 0.6 84 3 89.0 84.5 81.0 78.2 1.5 5 8 99.5 98.3 97.6 96.6 0.8 1 8 99.5 98.3 97.6 96.6 0.8 1 5 86.0 78.1 74.9 70.0 3.0 1 5 86.0 78.1 74.9 70.0 3.0 1 3 83.3 83.3 83.3 15.2 0 1 3 60.0 53.7 50.3 47.0 1.8 18 6 74.2 69.0 64.9 61.2 0.9 22 90.4 86.7 83.6 81.3 0.5 44	73.6 89.0 89.5 86.0		76.8			250	493 407	11	8585	397	278	653	328
3 89.0 84.5 81.0 78.2 1.5 5 8 99.5 98.3 97.6 96.6 0.8 1 5 86.0 78.1 74.9 70.0 3.0 1 5 86.0 78.1 74.9 70.0 3.0 1 3 83.3 83.3 83.3 15.2 0 1 3 60.0 53.7 50.3 47.0 1.8 18 2 6 74.2 69.0 64.9 61.2 0.9 22 5 90.4 86.7 83.6 81.3 0.5 44 8	89.0 99.5 86.0		56.9			235	746 437	25	3493	558	139	510	248
8 99.5 98.3 97.6 96.6 0.8 1 5 86.0 78.1 74.9 70.0 3.0 1 3 83.3 83.3 83.3 83.3 15.2 0 3 60.0 53.7 50.3 47.0 1.8 18 2 6 74.2 69.0 64.9 61.2 0.9 22 5 90.4 86.7 83.6 81.3 0.5 44 8	99.5 86.0		78.2	1.5	5	×	8 17	7	523	25	23	51	22
5 86.0 78.1 74.9 70.0 3.0 1 3 83.3 83.3 83.3 83.3 15.2 0 3 60.0 53.7 50.3 47.0 1.8 18 6 74.2 69.0 64.9 61.2 0.9 22 90.4 86.7 83.6 81.3 0.5 44	86.0	97.6	96.6	0.8	-	0	2	0	538	0	4	9	Ś
3 83.3 83.3 83.3 83.3 83.3 15.2 0 3 60.0 53.7 50.3 47.0 1.8 18 6 74.2 69.0 64.9 61.2 0.9 22 2 90.4 86.7 83.6 81.3 0.5 44		74.9	70.0	3.0	1	7	5 3	0	138	Ś	19	23	12
3 60.0 53.7 50.3 47.0 1.8 18 6 74.2 69.0 64.9 61.2 0.9 22 2 90.4 86.7 83.6 81.3 0.5 44	83.3	83.3		15.2	0	0	0 0	0	S	0	1	0	0
975 22 134 71.3 60.0 53.7 50.3 47.0 1.8 18 3412 30 524 83.6 74.2 69.0 64.9 61.2 0.9 22 8712 16 1096 95.2 90.4 86.7 83.6 81.3 0.5 44	es)												
3412 30 524 83.6 74.2 69.0 64.9 61.2 0.9 22 8712 16 1096 95.2 90.4 86.7 83.6 81.3 0.5 44	60.0	50.3	47.0		18	29	61 36	2	314	139	30	75	42
8712 16 1096 95.2 90.4 86.7 83.6 81.3 0.5 44	74.2		61.2		22	54	187 92	4	1479	279	75	256	141
	95.2 90.4 86.7	83.6	81.3	0.5	44	83	211 167	10	5512	165	178	402	156
D2 10,559 26 1168 92.0 83.1 76.3 71.7 68.4 0.5 102 29.	83.1	71.7	68.4			295	725 520	20	5586	340	170	458	248
D2+ 563 3 63 88.8 76.9 70.9 64.1 60.7 2.2 5 2	76.9	64.1	60.7	2.2	5	24	49 37	2	266	30	4	30	11
(resected cases)													
- 16,805 63 2180 92.6 86.0 81.5 78.1 75.4 0.4 112 26	86.0		75.4			265	646 440	16	9706	556	316	719	396

(continue
Table 3

Categories Total		Direct	Lost	Postop	Postoperative survival rate (%)	rvival rate	(%)		S.E	Site of 1	Site of recurrence	e			Alive	Cause	Cause of death		
u	number	death	f.u	1 yr	2 yr	3 yr	4 yr	5 yr	at 5 yr	Г	ΓN	Р	Н	R		PD	00	OD	UK
+	7734	37	852	87.5	77.3	70.0	64.4	60.7	0.6	84	230	608	425	22	3574	429	148	336	218
Combined resected organ (resected cases)	tected of	rgan (res	ected cas	es)															
Pancreatic tail	298	ŝ	33	74.8	57.0	50.9	44.6	41.6	3.1	S	18	4	24	б	96	25	7	25	9
Spleen	1693	5	156	86.1	73.5	64.4	58.2	53.6	1.3	28	68	196	142	6	703	78	20	93	37
Transverse colon	158	ŝ	16	70.8	57.8	49.5	41.5	41.5	4.2	ŝ	4	35	∞	0	50	20	1	8	2
Transverse mesoco- lon	88	$\tilde{\mathbf{\omega}}$	10	73.6	58.0	47.4	37.9	33.4	5.5	4	Ś	18	9	0	20	L	0	Ŷ	4
Dia- phragm	18	0	5	77.1	65.3	65.3	52.2	52.2	12.3	0	0	7	0	0	8	4	0	0	0
Thoracic esopha- gus	83	0	11	75.8	59.4	40.6	34.7	31.5	5.6	-	×	4	11	0	19	6	7	7	1
Liver	175	1	17	78.9	64.1	54.7	46.9	45.4	4.1	1	5	12	23	0	62	24	4	8	7
Gall blad- der	4959	22	573	90.3	81.7	75.2	70.3	66.7	0.7	39	115	284	203	٢	2502	240	98	255	152
Adrenal gland	10	0	1	88.9	88.9	88.9	88.9	88.9	10.5	0	0	0	0	0	٢	0	0	0	1
Kidney	17	0	С	100	100	100	84.6	84.6	10.0	0	0	1	0	0	10	1	0	0	0
Small intestine	46	1	×	67.1	61.9	56.4	56.4	56.4	7.8	1	1	1	1	1	18	9	1	Ś	1
Abdomi- nal wall	×	0	1	75.0	62.5	50.0	37.5	37.5	17.1	0	0	1	1	0	7	1	0	1	1
Ovary	19	0	2	88.6	76.4	63.6	63.6	57.3	12.3	0	0	б	1	0	6	ю	0	0	0
Appleby's opera- tion	ς	0	0	66.7	33.3	33.3	33.3	33.3	27.2	0	0	0	0	0	1	0	1	0	1
Pancrea- tico-duo- denec- tomy	39	0	Ś	83.6	71.8	53.1	53.1	43.1	8.7	0	6	ς	1	0	13	ŝ	S.	ς	0
Others	120	5	14	91.2	88.1	72.4	6.99	62.3	5.0	7	4	4	7	0	54	9	L	9	5
Involvement of the resection margin (resected cases)	of the re.	section r	nargin (re	esected c	ises)														
PM- and 27	23,759	85	2953	91.9	84.5	79.3	75.3	72.3	0.3	164	464	1123	820	31	13,134	822	451	1199	581

(continued)	
Table 3	

			(21)												
1 yr	1 yr 2 yr 3 yr		4 yr 5 yr at 5 yr L LN	5 yr	at 5 yr	Г	ΓN	Р	Н	К		PD	00	OC OD	UK
64 60.1 40.3	40.3	29.3	24.1	20.2	1.8	29	29	120	38	9	90 143	143	5	29	28
94.6	88.8	83.9	80.1	77.0	0.3	130	351	733	662	26	12,988	353	442	1106	516
70.0	45.1	32.4	25.3	21.4	1.3	35	68	286	100	б	186	190	11	62	4
48.8	24.5	16.0	12.1	9.4	1.0	29	69	227	96	L	74	413	6	60	46
operative	e days, L	ost f.u. lo	st to follo	w-up, SE	standard	error, L	local, LN	lymph no	de, P pe	ritoneum.	, H liver, R	recurren	ce at kno	wn site, I	D prin
9 <u>7</u> 9	4.6 0.0 8.8 8.8 ×, UK ч	 773 94.6 88.8 113 70.0 45.1 128 48.8 24.5 30 postoperative days, <i>L</i> her disease, <i>UK</i> unknown 	4.6 88.8 83.9 0.0 45.1 32.4 8.8 24.5 16.0 berative days, <i>Lost f.u. lo</i> <i>s. UK</i> unknown, <i>PM</i> prox	 4.6 88.8 83.9 80.1 0.0 45.1 32.4 25.3 8.8 24.5 16.0 12.1 berative days, Lost f.u. lost to follo berative days, Lost f.u. lost to follo berative days, Lost f.u. lost to follo 	 4.6 88.8 83.9 80.1 77.0 0.0 45.1 32.4 25.3 21.4 8.8 24.5 16.0 12.1 9.4 Berative days, Lost f.u. lost to follow-up, SE 2. UK unknown, PM proximal margin, DM d 	 4.6 88.8 83.9 80.1 77.0 0.3 0.0 45.1 32.4 25.3 21.4 1.3 8.8 24.5 16.0 12.1 9.4 1.0 berative days, <i>Lost f.u. lost to follow-up</i>, <i>SE</i> standard 3. <i>UK</i> unknown, <i>PM</i> proximal margin, <i>DM</i> distal margin 	 4.6 88.8 83.9 80.1 77.0 0.3 130 0.0 45.1 32.4 25.3 21.4 1.3 35 8.8 24.5 16.0 12.1 9.4 1.0 29 berative days, <i>Lost f.u. lost to follow-up</i>, <i>SE</i> standard error, <i>L</i> 5, <i>UK</i> unknown, <i>PM</i> proximal margin, <i>DM</i> distal margin, <i>R0</i> n. 	 4.6 88.8 83.9 80.1 77.0 0.3 130 351 0.0 45.1 32.4 25.3 21.4 1.3 35 68 8.8 24.5 16.0 12.1 9.4 1.0 29 69 berative days, <i>Lost f.u. lost to follow-up</i>, <i>SE</i> standard error, <i>L</i> local, <i>LN</i> bruknown, <i>PM</i> proximal margin, <i>DM</i> distal margin, <i>R0</i> no residual 	 4.6 88.8 83.9 80.1 77.0 0.3 130 351 733 0.0 45.1 32.4 25.3 21.4 1.3 35 68 286 8.8 24.5 16.0 12.1 9.4 1.0 29 69 227 berative days, <i>Lost f.u. lost to follow-up</i>, <i>SE</i> standard error, <i>L</i> local, <i>LN</i> lymph no <i>v</i>, <i>UK</i> unknown, <i>PM</i> proximal margin, <i>DM</i> distal margin, <i>R0</i> no residual tumor, <i>R</i> 	 4.6 88.8 83.9 80.1 77.0 0.3 130 351 733 662 0.0 45.1 32.4 25.3 21.4 1.3 35 68 286 100 8.8 24.5 16.0 12.1 9.4 1.0 29 69 227 96 berative days, <i>Lost f.u. lost to follow-up</i>, <i>SE</i> standard error, <i>L</i> local, <i>LN</i> lymph node, <i>P</i> perative days, <i>Lost f.u. lost to follow-up</i>, <i>SE</i> standard error, <i>L</i> local, <i>LN</i> lymph node, <i>P</i> perative days, <i>Lost f.u. lost to follow-up</i>, <i>SE</i> standard error, <i>L</i> local, <i>LN</i> lymph node, <i>P</i> perative days, <i>Lost f.u. lost to follow-up</i>, <i>SE</i> standard error, <i>L</i> local, <i>LN</i> lymph node, <i>P</i> perative days, <i>Lost f.u. lost to follow-up</i>, <i>SE</i> standard error, <i>L</i> local, <i>LN</i> lymph node, <i>P</i> perative days, <i>Lost f.u.</i> lost to follow-up, <i>SE</i> standard error, <i>L</i> local, <i>LN</i> lymph node, <i>P</i> perative days, <i>Lost f.u.</i> lost to follow-up, <i>SE</i> standard error, <i>L</i> local, <i>LN</i> lymph node, <i>P</i> perative days, <i>Lost f.u.</i> lost to follow-up, <i>SE</i> standard error, <i>L</i> local, <i>LN</i> lymph node, <i>P</i> perative days, <i>Lost f.u.</i> lost to follow-up, <i>SE</i> standard error, <i>L</i> local, <i>LN</i> lymph node, <i>P</i> perative days, <i>Lost f.u.</i> lost to follow-up, <i>SE</i> standard error, <i>L</i> local, <i>LN</i> lymph node, <i>P</i> perative days, <i>Lost f.u.</i> lost to follow-up, <i>SE</i> standard error, <i>L</i> local, <i>LN</i> lymph node, <i>P</i> perative days, <i>Lost f.u.</i> lost to follow-up, <i>SE</i> standard error, <i>L</i> local, <i>LN</i> lymph node, <i>P</i> perative days, <i>Lost f.u.</i> lost to follow-up, <i>SE</i> standard error, <i>L</i> local, <i>LN</i> lymph node, <i>P</i> perative days, <i>Lost f.u.</i> lost to follow-up, <i>R</i> distal margin, <i>R0</i> no residual tumor, <i>R1</i> microsc 	 4.6 88.8 83.9 80.1 77.0 0.3 130 351 733 662 26 0.0 45.1 32.4 25.3 21.4 1.3 35 68 286 100 3 8.8 24.5 16.0 12.1 9.4 1.0 29 69 227 96 7 berative days, <i>Lost f.u. lost to follow-up</i>, <i>SE</i> standard error, <i>L</i> local, <i>LN</i> lymph node, <i>P</i> peritoneum 2. <i>UK</i> unknown, <i>PM</i> proximal margin, <i>DM</i> distal margin, <i>R0</i> no residual tumor, <i>R1</i> microscopic resi 	 4.6 88.8 83.9 80.1 77.0 0.3 130 351 733 662 26 12,988 0.0 45.1 32.4 25.3 21.4 1.3 35 68 286 100 3 186 8.8 24.5 16.0 12.1 9.4 1.0 29 69 227 96 7 74 be rative days, <i>Lost f.u. lost to follow-up</i>, <i>SE</i> standard error, <i>L</i> local, <i>LN</i> lymph node, <i>P</i> peritoneum, <i>H</i> liver, <i>R</i> b. <i>UK</i> unknown, <i>PM</i> proximal margin, <i>DM</i> distal margin, <i>R0</i> no residual tumor, <i>RI</i> microscopic residual tumor (7.1 100 100 100 100 100 100 100 100 100 1	 4.6 88.8 83.9 80.1 77.0 0.3 130 351 733 662 26 12,988 353 0.0 45.1 32.4 25.3 21.4 1.3 35 68 286 100 3 186 190 8.8 24.5 16.0 12.1 9.4 1.0 29 69 227 96 7 74 413 	 4.6 88.8 83.9 80.1 77.0 0.3 130 351 733 662 26 12,988 353 442 0.0 45.1 32.4 25.3 21.4 1.3 35 68 286 100 3 186 190 11 8.8 24.5 16.0 12.1 9.4 1.0 29 69 227 96 7 74 413 9 erative days, <i>Lost fu. lost to follow-up</i>, <i>SE</i> standard error, <i>L</i> local, <i>LN</i> lymph node, <i>P</i> peritoneum, <i>H</i> liver, <i>R</i> recurrence at knc v. <i>UK</i> unknown, <i>PM</i> proximal margin, <i>DM</i> distal margin, <i>R0</i> no residual tumor, <i>R1</i> microscopic residual tumor (positive resection) 	83.9 80.1 77.0 0.3 130 351 733 662 26 12,988 353 442 32.4 25.3 21.4 1.3 35 68 286 100 3 186 190 11 16.0 12.1 9.4 1.0 29 69 227 96 7 74 413 9 Lost fu. lost to follow-up, SE standard error, L local, LN lymph node, P peritoneum, H liver, R recurrence at known n, PM proximal margin, DM distal margin, R0 no residual tumor, R1 microscopic residual tumor (positive resection m

macroscopic residual tumor

pylorus preserving gastrectomy, segmental gastrectomy, and local gastrectomy (including wedge resection), were recorded in the NCD database at 2011 [9]. In the NCD gastric cancer registry, the 24,539 resected cases with the above procedures covered 44.4% of stomach surgeries. The number of enrolled cases in gastric cancer registry accounted for less than half of stomach surgeries in NCD. The difficulty in achieving complete enumeration of all cancer patients is a major issue in organ-specific cancer registries. So far, the conventional JGCA registry has been voluntarily supported by the hospitals to which JGCA members belong, and so the increase in the number of participating hospitals has limitations. The launch of the NCD cancer registry has been widely announced to all hospitals that participated in the NCD surgery registry, as well as the 199 hospitals (39.7%) that newly participated in the initial NCD gastric cancer registry in addition to 302 conventional hospitals (60.3%). The NCD database showed high similarity to the conventional JGCA registry database [1]. The NCD cancer registry, which used a new registry system, demonstrated the validity of database construction. The NCD registry can be expected to expand the range of the gastric cancer registry and increase the number of hospitals participating in the cancer registry.

Another issue raised in the initial registry was the quality assurance of the registration data. An audit of the registration data of the gastroenterological surgeries in the NCD was started in 2015, and high accuracy of data entry has been proved through quality verification [14]. With regards to gastric cancer registry in the NCD, registrants failed to finish or approve data entry in 8.8% of all recorded cases, and did not enter follow-up data in 1.2% of the approved cases. These data deficiencies are also a limitation of this study. An entry system needs to become well known and should be modified for its easy-to-use application through validation by an audit. The complementary integration and reorganization of registry systems between organ-specific cancer registries containing detailed data about tumor status and other cancer registries containing prognostic information is required for conducting an accurate and reliable nationwide cancer database. If all the above-mentioned surgeries registered in the NCD are enrolled in the gastric cancer registry and provided prognostic information, complete enumeration of all stomach surgeries patients is possible.

In conclusion, the NCD registry system of gastric cancer demonstrated the validity of database construction. This program is expected to provide a new comprehensive cancer database integrating patient demographics, oncological features, and therapeutic outcomes with the optimization of data entry system. Therefore, the NCD registry system may offer useful information to further

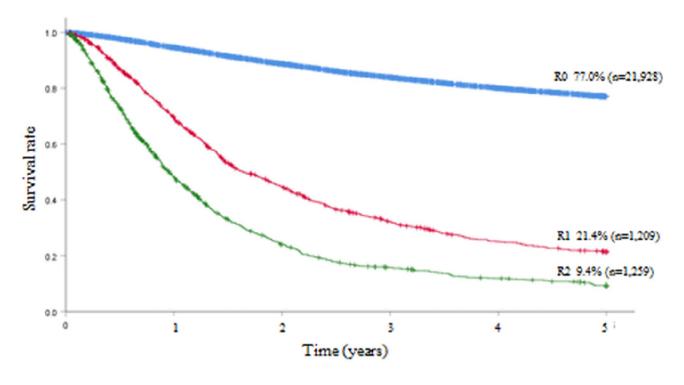


Fig. 3 Kaplan-Meier survival curves of patients stratified to residual tumor

develop gastric cancer research, and provide high-quality treatment.

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Declarations

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Human rights statement All procedures were performed in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national), as well as with the Helsinki Declaration of 1964 and later versions. The gastric cancer registration program of the NCD was approved by the Institutional Review Board of the Graduate School of Medicine, Kobe University.

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