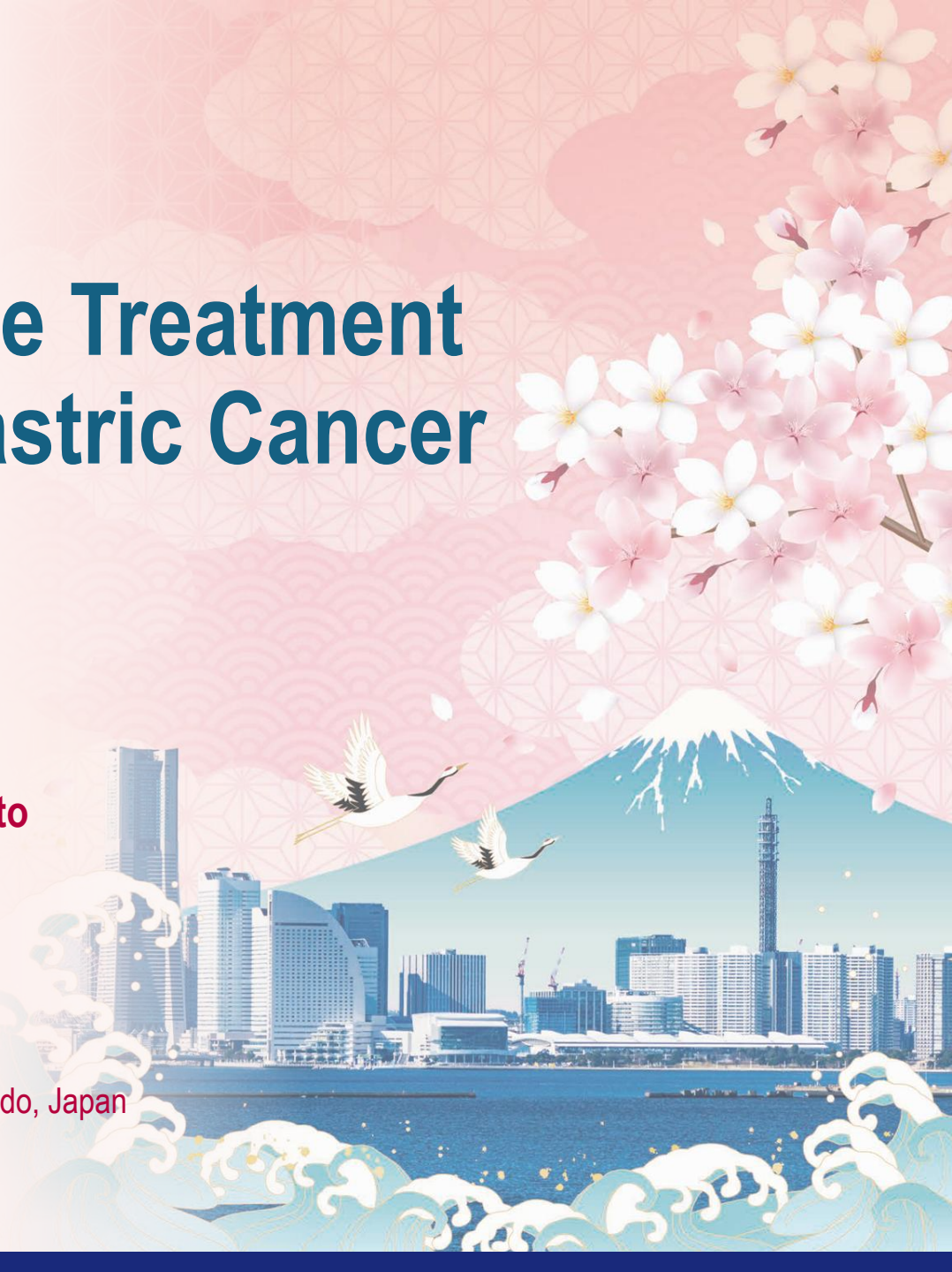
2026 the Japanese Society of Medical Oncology Annual Meeting

Medical Oncologists for Cancer Patients

Intensive Versus Less-Intensive Treatment Regimens in HER2-Positive Gastric Cancer Patients: A Database Analysis



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Background

- Gastric cancer is among the most prevalent malignancies in Japan,[1] with 112,881 new cases reported,[2] and HER2-positive gastric cancer accounting for approximately 5%–17% of cases[3]
- JGCA guidelines recommend intensive 1L T-mab–based chemotherapy (T-mab+Fp+Pt) for patients with HER2-positive gastric cancer[4]
- However, in real-world practice, elderly or frail patients often receive less-intensive regimens due to concerns regarding tolerability[4,5]
- This study analyzed real-world treatment patterns and outcomes of intensive versus less-intensive T-mab–based regimens in Japanese patients with HER2-positive gastric cancer

1L, first line; Fp, fluoropyrimidine; HER2, human epidermal growth factor receptor 2; JGCA, Japanese Gastric Cancer Association; Pt, platinum; T-mab, trastuzumab

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Methods

Study design
Retrospective cohort study (UMIN000056537) using the MDV claims database

Population
Adults (≥18 years) with gastric cancer who received T-mab–based 1L therapy

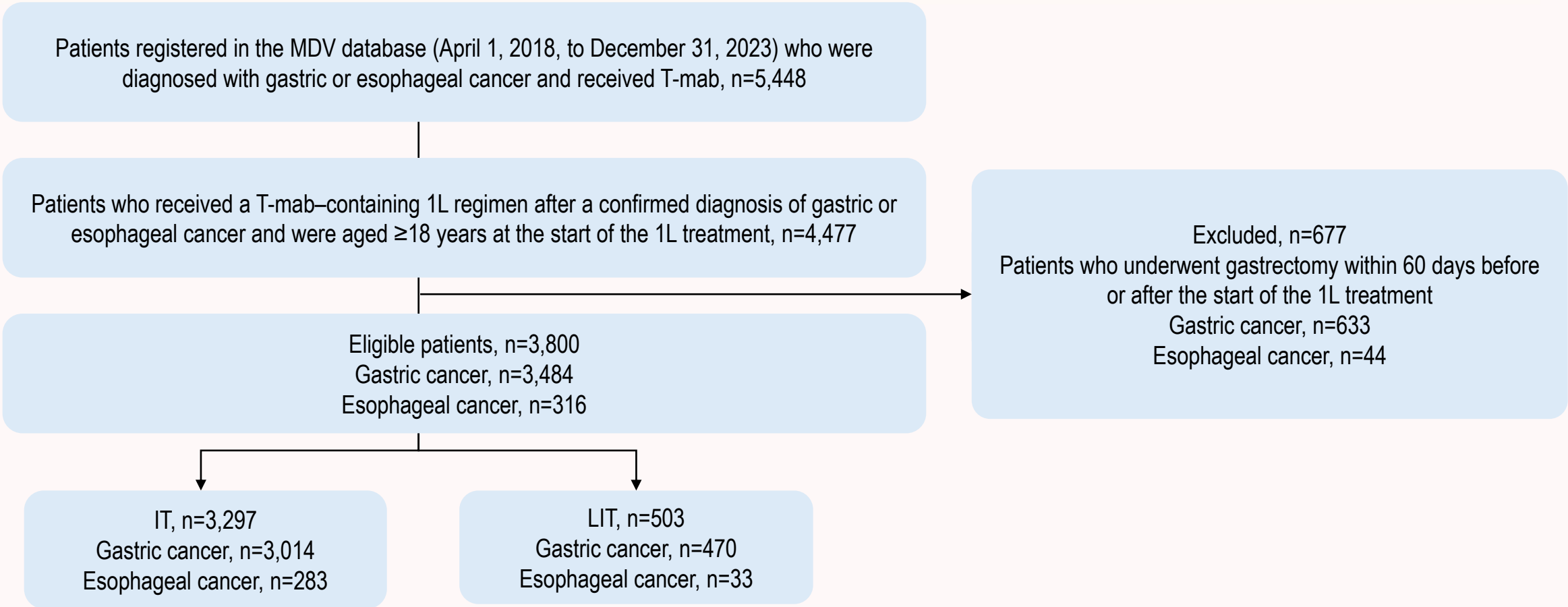
Treatment groups
IT group: T-mab+Fp+Pt
LIT group: T-mab only or with Fp or Pt

Outcomes
Proportion of patients receiving each treatment regimen (overall and LIT/IT), OTD*, and TTF

Note: Esophageal cancer was included to encompass gastroesophageal junction cancers. *Multivariable analysis of factors associated with OTD was performed and factors were identified which include treatment intensity (less-intensive vs. intensive), age (≥80 vs. <80 years), sex (male vs. female), BMI (<18.5 vs. ≥18.5 kg/m² and missing vs. <18.5 kg/m²), ADL independence (independent vs. dependent), surgery history (yes vs. no), metastatic sites including peritoneal or ascites, liver, lymph node, lung, bone, and brain metastases (yes vs. no), comorbidities such as hypertension, diabetes, liver disease, thrombosis, ischemic heart disease, renal disease, and lung disease (pneumonia) (yes vs. no), supportive care factors including antiemetic care, dietary consultation, and physical therapy (yes vs. no), hospital environment factors such as treatment at a designated cancer hospital (yes vs. no), hospital size (<500 vs. ≥500 beds), and clinical department (surgery vs. internal medicine; others vs. internal medicine). 1L, first line; ADL, activities of daily living; BMI, body mass index; Fp, fluoropyrimidine; IT, intensive treatment; LIT, less-intensive treatment; MDV, Medical Data Vision; OTD, overall therapy duration; Pt, platinum; T-mab, trastuzumab; TTF, time to treatment failure.

Patient disposition

Out of 3,800 eligible patients, 3,297 (86.8%) received the IT regimen and 503 (13.2%) received the LIT regimen



1L, first line; IT, intensive treatment; LIT, less-intensive treatment; MDV, Medical Data Vision; T-mab, trastuzumab

Baseline characteristics

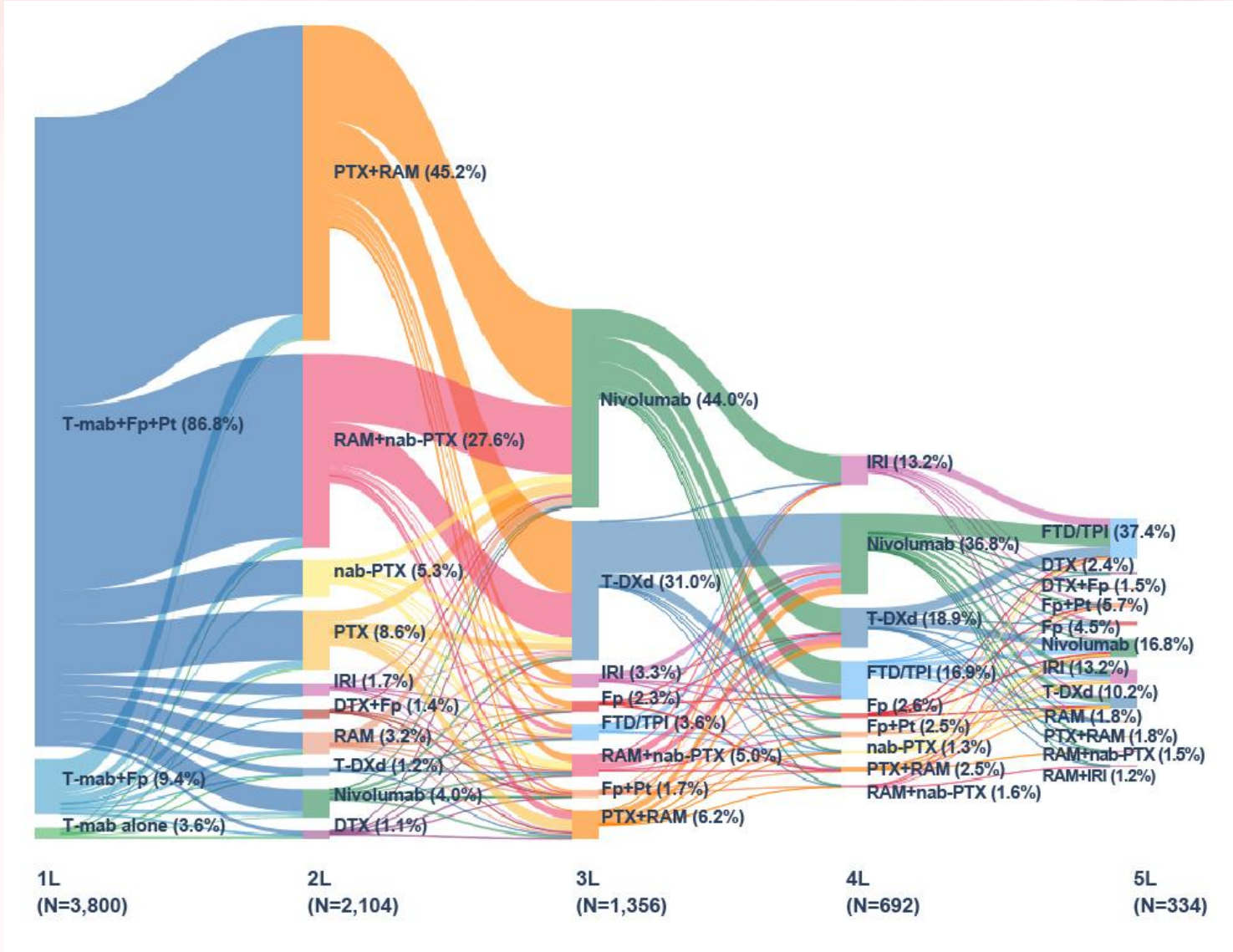
Characteristic	Total (N=3,800)	LIT (n=503)	IT (n=3,297)	P Value
Age, years, at 1L, n (%)				
<80	3,319 (87.3)	330 (65.6)	2,989 (90.7)	< 0.001
≥80	481 (12.7)	173 (34.4)	308 (9.3)	-
Sex, n (%)				
Male	2,952 (77.7)	334 (66.4)	2,618 (79.4)	< 0.001
Female	848 (22.3)	169 (33.6)	679 (20.6)	-
ADL, n (%)				
Independent	2,642 (69.5)	214 (42.5)	2,428 (73.6)	< 0.001
Surgical history, n (%)				
Yes	42 (1.1)	9 (1.8)	33 (1.0)	0.115
No	3,758 (98.9)	494 (98.2)	3,264 (99.0)	-
Supportive care, n (%)				
Antiemetic care	3,275 (86.2)	236 (46.9)	3,039 (92.2)	< 0.001
Dietary consultation	673 (17.7)	72 (14.3)	601 (18.2)	0.032
Physical therapy	488 (12.8)	89 (17.7)	399 (12.1)	< 0.001
BMI, kg/m^2, n (%)				
≥18.5	2,454 (64.6)	200 (39.8)	2,254 (68.4)	-
<18.5	529 (13.9)	61 (12.1)	468 (14.2)	< 0.001
Missing	817 (21.5)	242 (48.1)	575 (17.4)	-
Hospital size, n (%)				
<500 beds	2,244 (59.1)	305 (60.6)	1,939 (58.8)	0.438

Characteristic	Total (N=3,800)	LIT (n=503)	IT (n=3,297)	P Value
Cancer hospital, n (%)				
Yes	3,216 (84.6)	422 (83.9)	2,794 (84.7)	0.624
Clinical department, n (%)				
Surgery	2,322 (61.1)	238 (47.3)	2,084 (63.2)	-
Internal medicine	1,422 (37.4)	237 (47.1)	1,185 (35.9)	< 0.001
Other	56 (1.5)	28 (5.6)	28 (0.8)	-
Metastasis sites, n (%)				
Liver	1,055 (27.8)	122 (24.3)	933 (28.3)	0.059
Lymph node	730 (19.2)	92 (18.3)	638 (19.4)	0.574
Peritoneal or ascites	485 (12.8)	54 (10.7)	431 (13.1)	0.143
Lung	280 (7.4)	42 (8.3)	238 (7.2)	0.366
Bone	157 (4.1)	26 (5.2)	131 (4.0)	0.209
Brain	33 (0.9)	6 (1.2)	27 (0.8)	0.400
Comorbidities, n (%)[a]				
Hypertension	1,159 (30.5)	181 (36.0)	978 (29.7)	0.004
Diabetes	897 (23.6)	124 (24.7)	773 (23.4)	0.553
Liver disease	706 (18.6)	108 (21.5)	598 (18.1)	0.073
Thrombosis	49 (1.3)	13 (2.6)	36 (1.1)	0.006
Ischemic heart disease	301 (7.9)	57 (11.3)	244 (7.4)	0.002
Renal disease	275 (7.2)	49 (9.7)	226 (6.9)	0.020
Lung disease, pneumonia	63 (1.7)	16 (3.2)	47 (1.4)	0.004

[a]These patients may be included in more than one category. 1L, first line; ADL, activities of daily living; BMI, body mass index; P, probability

Proportion of patients receiving each treatment regimen (overall)

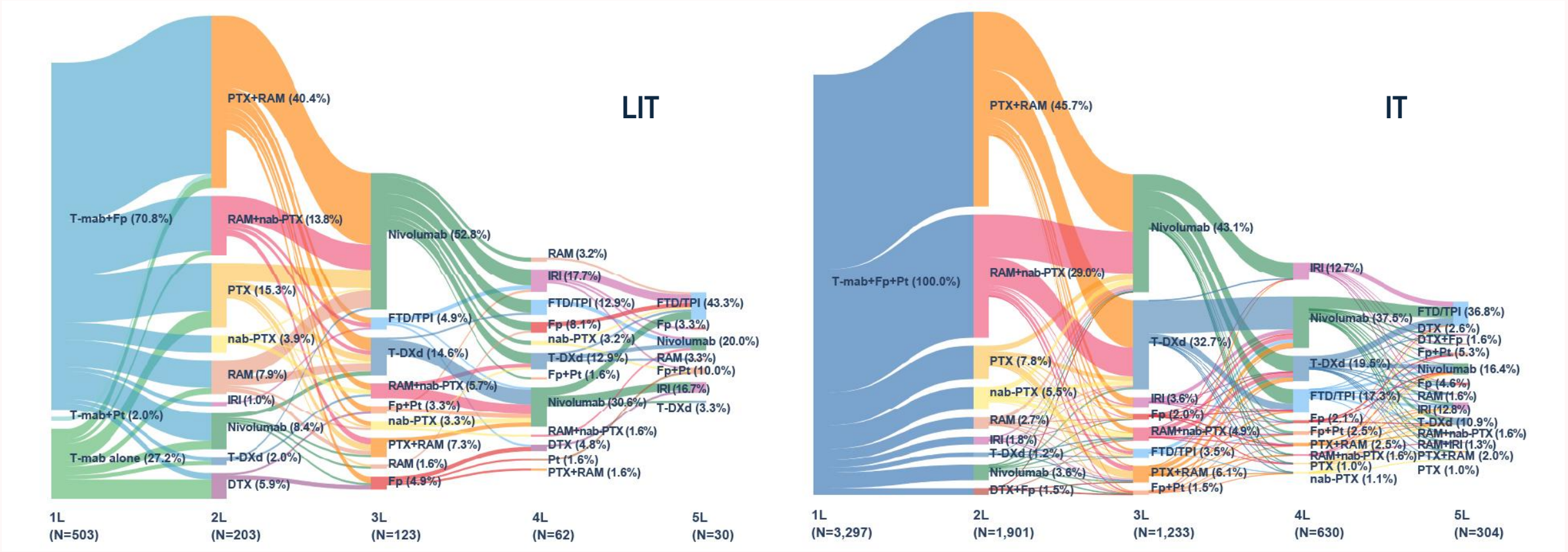
Among patients receiving 1L therapy (N=3,800), LIT regimens (T-mab alone, T-mab+Fp, T-mab+Pt) accounted for 13.2% (3.6%, 9.4%, and 0.3%, respectively), whereas the remaining 86.8% received an IT regimen



1L, first line; 2L, second line; 3L, third line; 4L, fourth line; 5L, fifth line; DTX, docetaxel; Fp, fluoropyrimidine; FTD/TPI, trifluridine/tipiracil; IRI, irinotecan; IT, intensive treatment; LIT, less-intensive treatment; nab-PTX, albumin-conjugated paclitaxel; Pt, platinum; PTX, paclitaxel; RAM, ramucirumab; T-DXd, trastuzumab deruxtecan; T-mab, trastuzumab

Proportion of patients receiving each treatment regimen (LIT/IT)

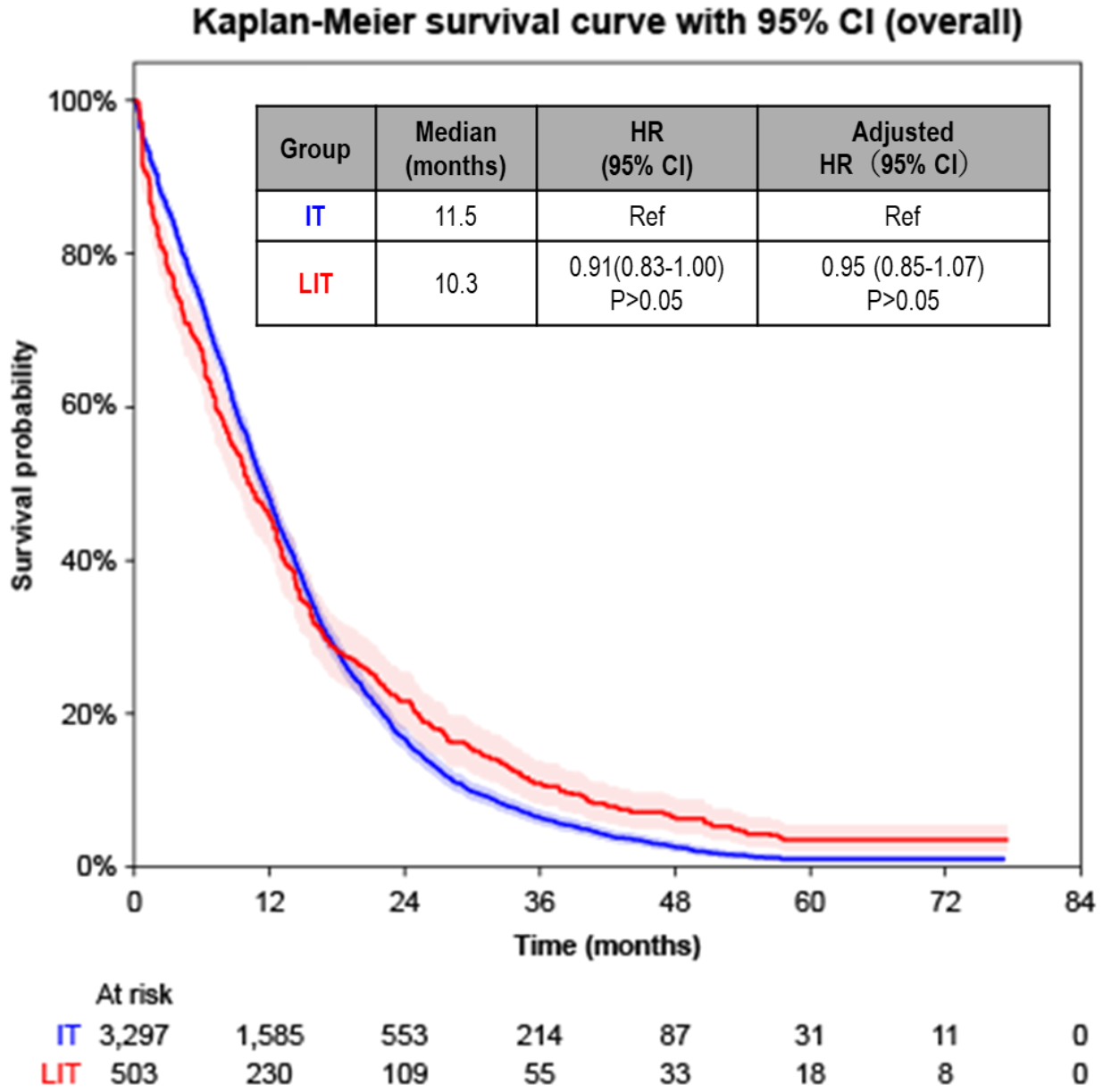
The proportion of patients receiving monotherapy as 2L treatment was higher in the LIT group (27.1%; PTX 15.3%, RAM 7.9%, nab-PTX 3.9%) than in the IT group (16.0%; PTX 7.8%, RAM 2.7%, nab-PTX 5.5%)



1L, first line; 2L, second line; 3L, third line; 4L, fourth line; 5L, fifth line; DTX, docetaxel; Fp, fluoropyrimidine; FTD/TPI, trifluridine/tipiracil; IRI, irinotecan; IT, intensive treatment; LIT, less-intensive treatment; nab-PTX, albumin-conjugated paclitaxel; Pt, platinum; PTX, paclitaxel; RAM, ramucirumab; T-DXd, trastuzumab deruxtecan; T-mab, trastuzumab

Overall therapy duration

Median OTD was 10.3 months in the LIT group and 11.5 months in the IT group;
the difference was not statistically significant (*P*>0.05)



Group	Median (months)	HR (95% CI)	Adjusted HR (95% CI)
IT	11.5	Ref	Ref
LIT	10.3	0.91(0.83-1.00) P>0.05	0.95 (0.85-1.07) P>0.05

Note: HR was derived from multivariable analysis. CI, confidence interval; HR, hazard ratio; IT, intensive treatment; LIT, less-intensive treatment; OTD, overall therapy duration, Ref, reference

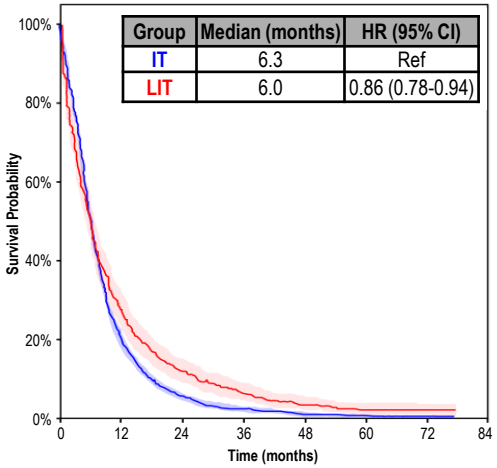
Time to treatment failure

- Across 1L–4L, the LIT was associated with longer TTF than IT, whereas in 5L the median TTF was similar with LIT vs IT (2.5 vs 2.1 months)

Kaplan-Meier curves with 95% CI (1L–5L)

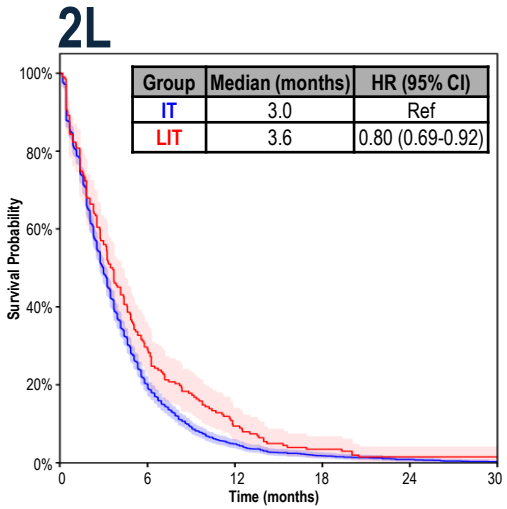
1L

Group	Median (months)	HR (95% CI)
IT	6.3	Ref
LIT	6.0	0.86 (0.78-0.94)



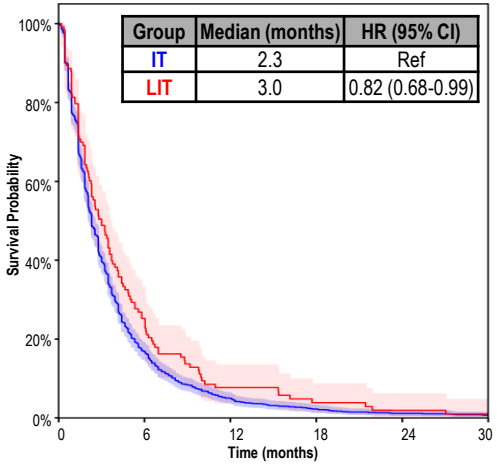
2L

Group	Median (months)	HR (95% CI)
IT	3.0	Ref
LIT	3.6	0.80 (0.69-0.92)



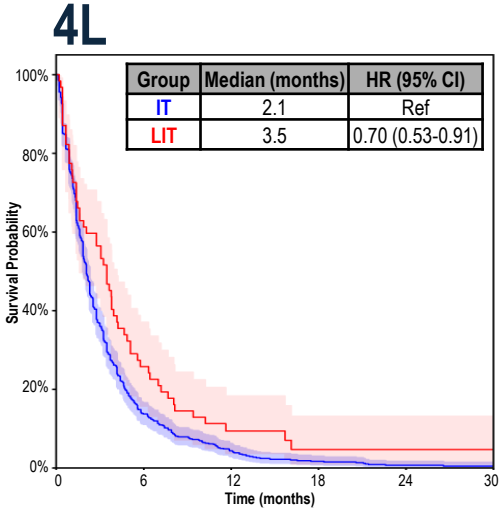
3L

Group	Median (months)	HR (95% CI)
IT	2.3	Ref
LIT	3.0	0.82 (0.68-0.99)



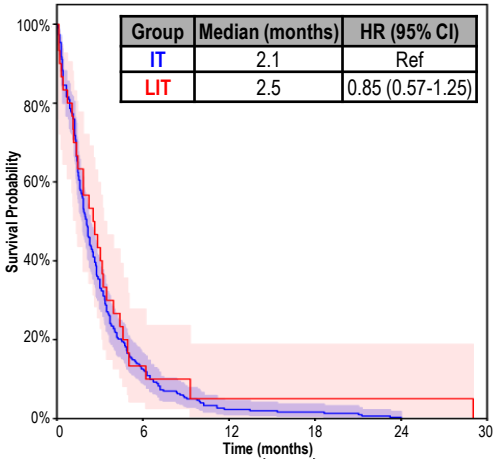
4L

Group	Median (months)	HR (95% CI)
IT	2.1	Ref
LIT	3.5	0.70 (0.53-0.91)



5L

Group	Median (months)	HR (95% CI)
IT	2.1	Ref
LIT	2.5	0.85 (0.57-1.25)



1L, first line; 2L, second line; 3L, third line; 4L, fourth line; 5L, fifth line; CI, confidence interval; HR, hazard ratio; IT, intensive treatment; LIT, less-intensive treatment; Ref, reference; TTF, time to treatment failure

Summary

- This large-scale, nationwide real-world study is the first in Japan comparing IT versus LIT regimens for HER2-positive gastric cancer across multiple therapy lines
- Most patients (86.8%) received an IT regimen, while a smaller proportion (13.2%) received an LIT regimen, which were more frequently chosen for elderly or vulnerable patients (≥80 years, female, ADL-dependent, and lower BMI)
- The proportion of patients receiving monotherapy as 2L treatment was higher in the LIT group than in the IT group
- Median OTD for the LIT group was comparable to that for the IT group
- TTF was longer in LIT than IT across 1L to 5L, whereas in 5L TTF was comparable between groups

1L, first line; 2L, second line; 4L, fourth line; 5L; fifth line; ADL, activities of daily living; BMI, body mass index; HER2, human epidermal growth factor receptor 2; HR, hazard ratio; IT, intensive treatment; LIT, less-intensive treatment; OTD, overall therapy duration; TTF, time to treatment failure

Conclusions

- This study suggests that LIT regimens (T-mab only or with Fp or Pt) might be important alternatives for patients with HER2-positive gastric cancer who are unsuitable for intensive therapy (T-mab+Fp+Pt)
- Future studies should further explore long-term outcomes to refine treatment strategies for patients who are elderly or vulnerable

Fp, fluoropyrimidines; HER2, human epidermal growth factor receptor 2; LIT, less-intensive treatment; Pt, platinum; T-mab, trastuzumab

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- De-identified and anonymized study participant data underlying the results presented in this presentation may be made available to researchers upon reasonable request to the presenting author. The decision to share the de-identified/anonymized study data will be made by the presenting author and the funder, Daiichi Sankyo Co., Ltd. Formal data sharing requests can be made up to 36 months from the presentation.