HER2 Regimen for Metastasis Gastric Cancer in ToGA trial and RWD experience sharing

Institute of Oncology, Chang Gung Memorial Hospital

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2021/05/01

Outlines

- HER2 and ToGA trial in gastric cancer
- Real world experience
- Case sharing

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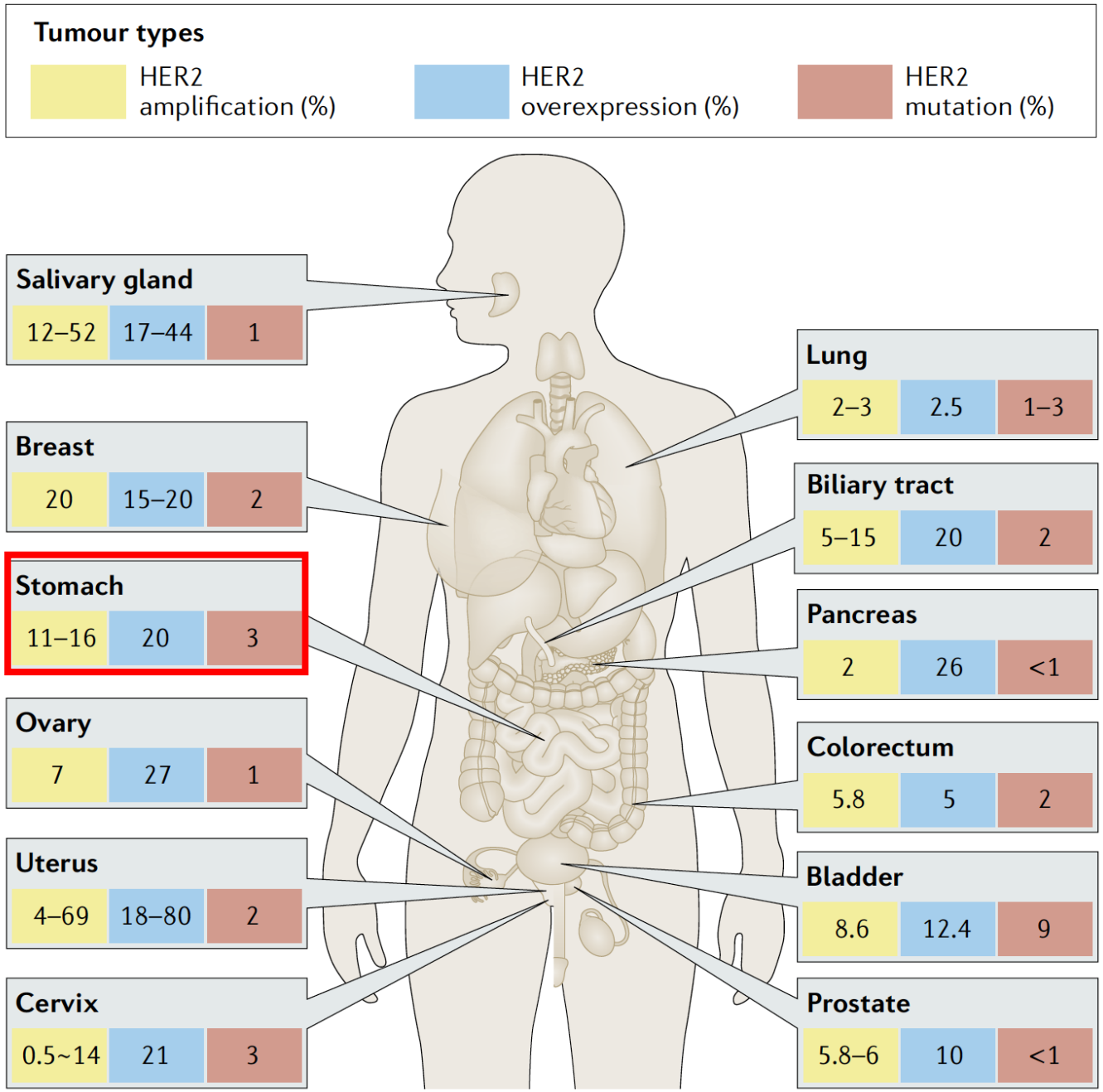


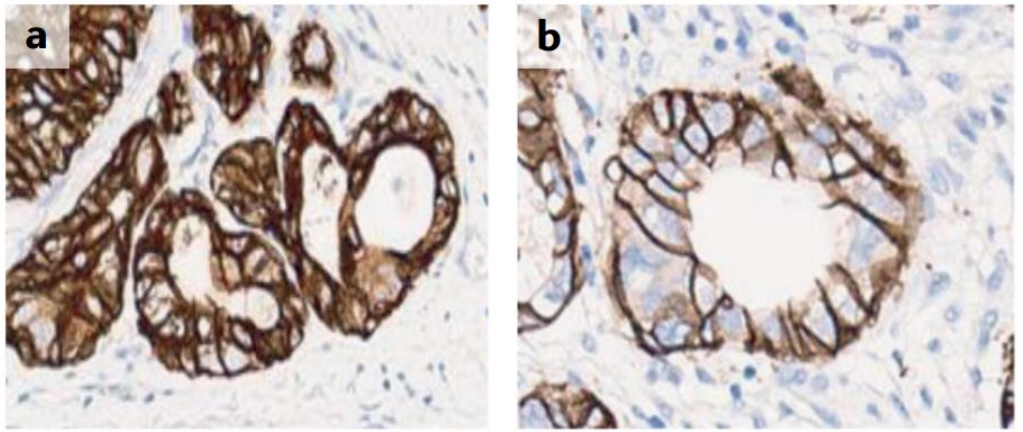


Fig. 3 | **HER2 expression in breast cancer and gastric cancer. a** | Complete membrane staining of HER2 in breast cancer. Magnification ×400. **b** | Basolateral membrane staining of HER2 in gastric cancer. Magnification ×400. Images in parts **a** and **b** courtesy of Professor W. H. Kim, Seoul National University College of Medicine, Republic of Korea.

Nature Reviews Clinical Oncology **volume 17**, pages33–48(2020)

The prevalence of HER2 in Taiwan

Study	Country	*n*	% HER-2$^+$ (definition)	Association	Prognostic factor
Tanner et al. (2005) [8]	Finland	131	12.2 (FISH +)	Intestinal type	Yes
Park et al. (2006) [16]	Korea	182	15.9 (IHC 2+ or 3+)	Intestinal type	Yes
Kim et al. (2007) [12]	Korea	248	22.6 (IHC 2+ or 3+)	Differentiation Intestinal type	Yes
Hoffman et al. (2008) [14]	Germany, China, Mexico	168	13.6 (IHC 3+ or IHC 2+ and FISH +)	Intestinal type	Not done
Barros-Silva et al. (2009) [10]	Portugal	463	9.3 (IHC 2+ or 3+)	Intestinal type Expansive type	Yes
Begnami et al. (2011) [15]	Brazil	221	12 (IHC 2+ or 3+)	Differentiation Intestinal type	Yes
Hsu et al. (2011), current series	Taiwan	1,036	6.1 (IHC 3+ or IHC 2+ and FISH +)	Differentiation	No

Abbreviations: FISH, fluorescence in situ hybridization; HER-2, human epidermal growth factor receptor 2; IHC, immunohistochemistry.

Hsu JT, *et al. Oncologist* 2011; 16:1706-13.

HER2 overexpression in GC: NTUH (N=329)

TABLE 1. Clinicopathologic and Molecular Characteristics of the 329 Gastric Carcinomas

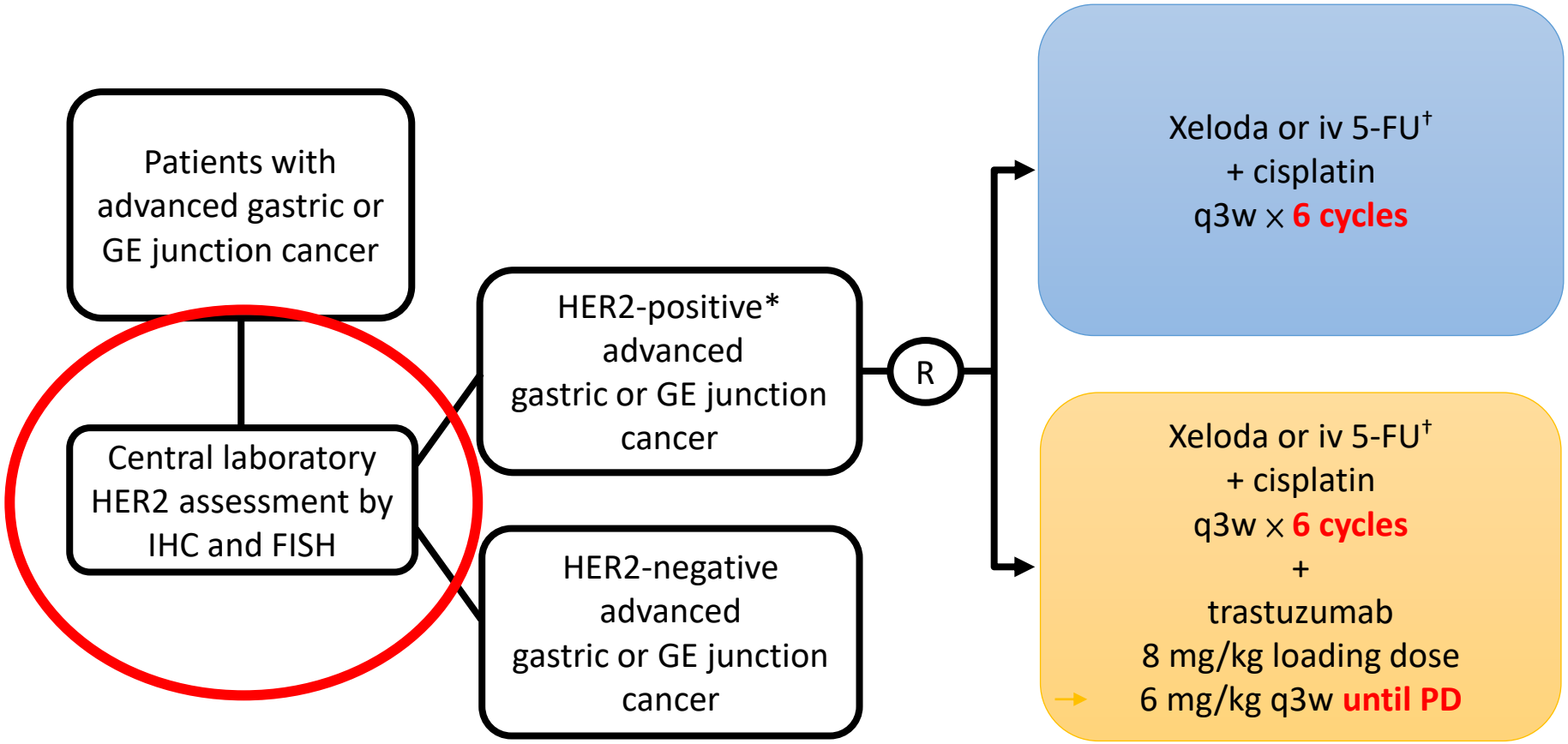
Clinical Features	N = 329, n (%)
Lymphovascular invasion	265 (81)
HER2 overexpression	16 (5)
ARID1A loss	54 (16)
E-cadherin loss	20 (6)
SATB2 expression	32 (10)
PMS2/MLH1-deficiency	40 (12)
MSH6/MSH2-deficiency	0
Positive EBV in situ hybridization	17 (5)
PD-L1 expression	44 (13)
DNA content abnormality	175 (53)

HER2: clone 4B5
Overexpression (3+): 5%

Tsai et al, Am J Surg Pathol 2020;44:1017-30

Randomised Phase III study: ToGA

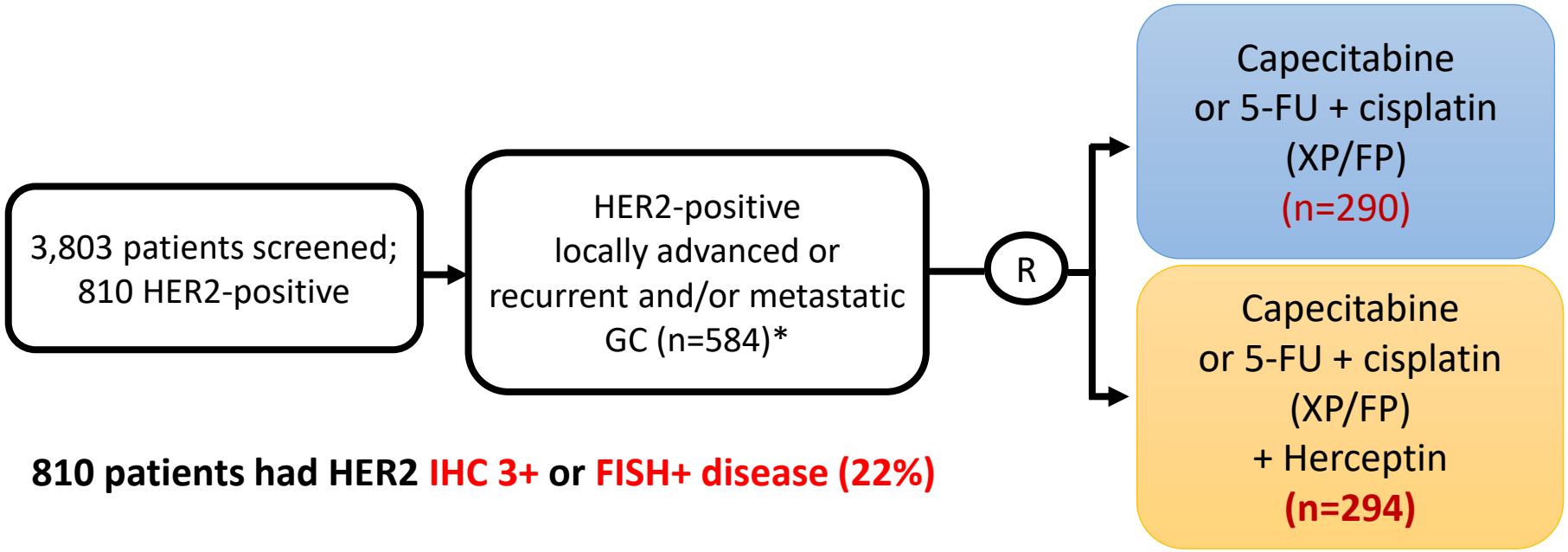
open-label, international, multicentre study



Herceptin: 8 mg/kg loading dose followed by 6 mg/kg q3w until disease progression
Cisplatin: 80 mg/m^2, D1, q3w x 6
Capecitabine: 1,000 mg/m^2 BID, D1–14, q3w x 6
5-FU: 800mg/m^2, D1-D5 continuous infusion, Q3w x 6

Bang & Van Cutsem et al 2010

ToGA trial design

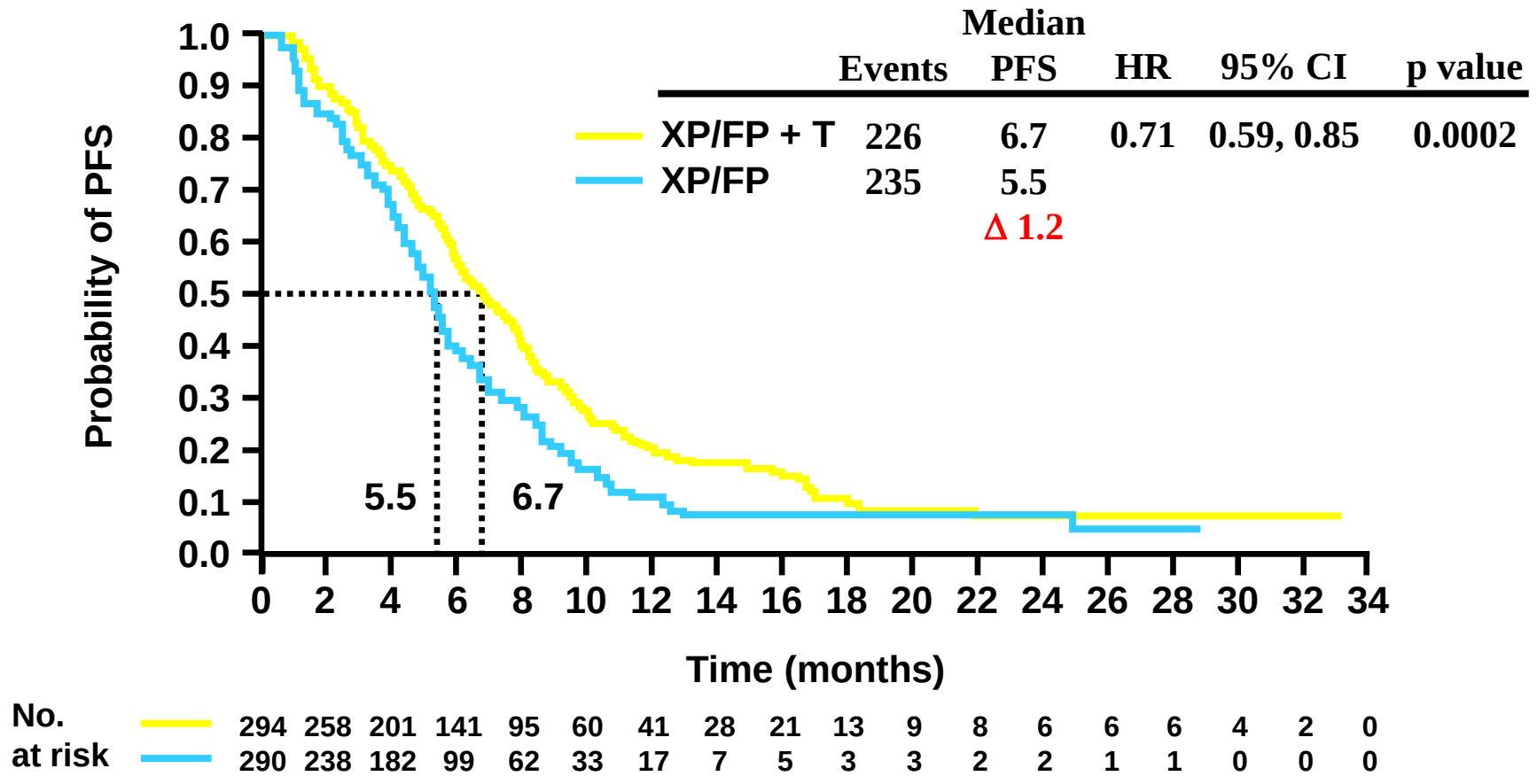


810 patients had HER2 IHC 3+ or FISH+ disease (22%)

- Primary objective: OS
- Secondary endpoints included:
  PFS, TTP, ORR, clinical benefit rate, duration of response, safety, quality of life, pain intensity, analgesic consumption

Bang & Van Cutsem et al 2010

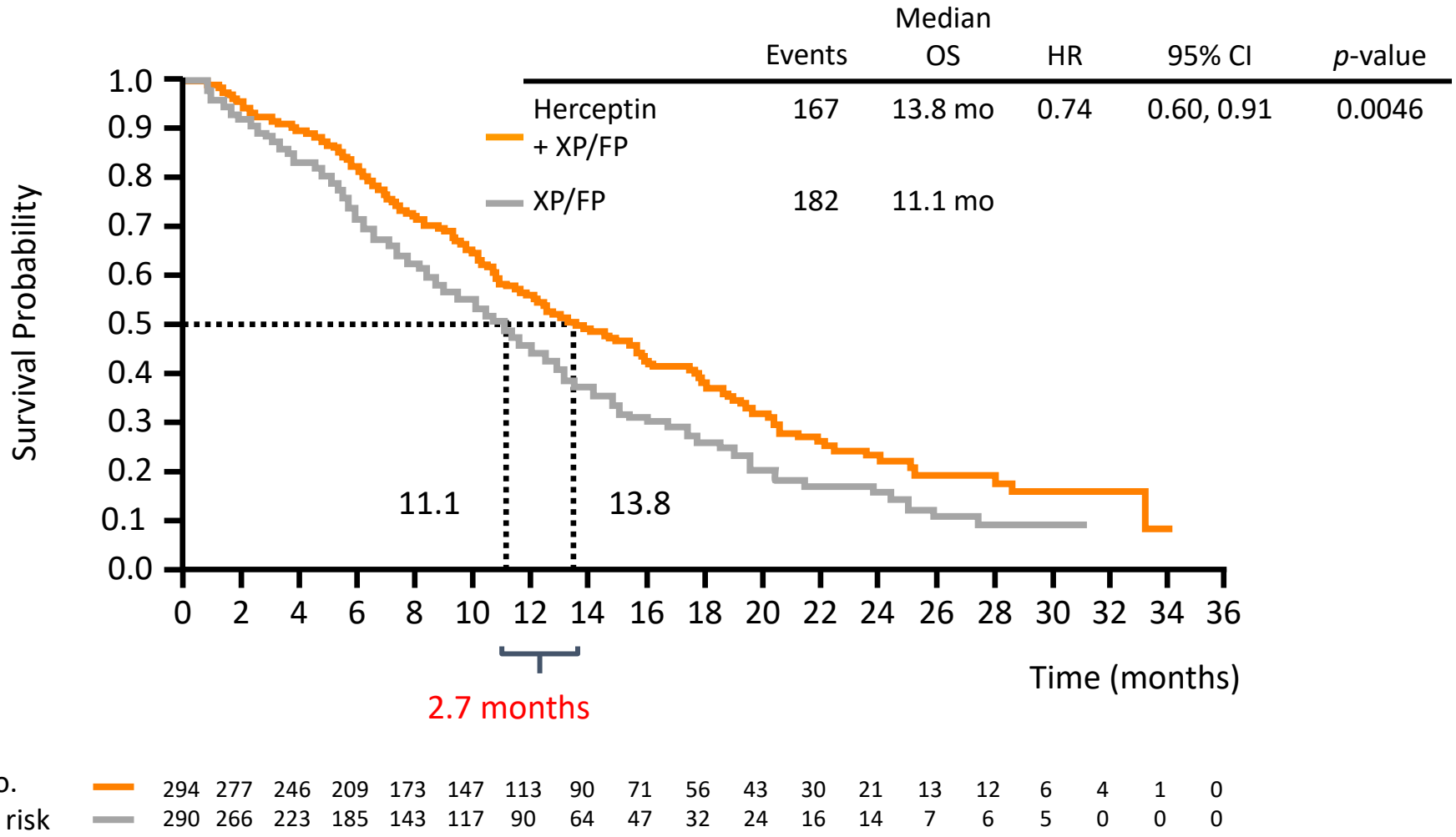
Herceptin significantly improved PFS- ITT population



Bang YJ, et al , Lancet 2010; 376: 687 – 97

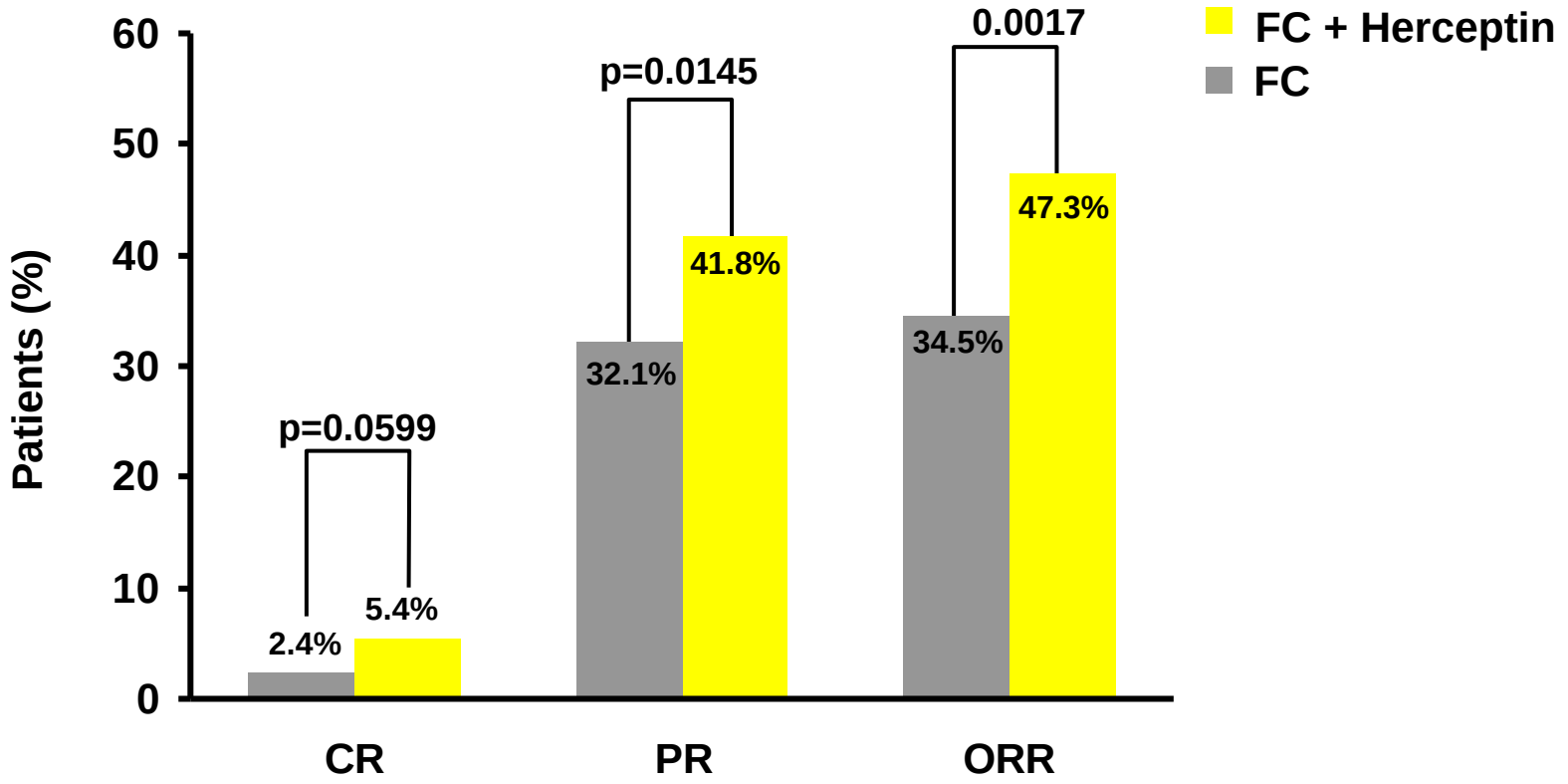
Primary Endpoint

Herceptin + XP/FP improves OS vs XP/FP alone - ITT population



Bang & Van Cutsem et al 2010

Herceptin significantly increase tumour response rate - ITT population



ORR = CR + PR
FC = fluoropyrimidine (5-FU or Xeloda) + cisplatin

Herceptin improves all efficacy parameters

Endpoint	Herceptin + XP/FP (n=294)	XP/FP (n=290)	HR (95% CI)	*p*-value
OS, median months[1]	13.8	11.1	0.74 (0.60, 0.91)	0.0046
PFS, median months[1]	6.7	5.5	0.71 (0.59, 0.85)	0.0002
TTP, median months[1]	7.1	5.6	0.70 (0.58, 0.85)	0.0003
ORR, %[1]	47	35	1.70* (1.22, 2.38)	0.0017
Patients with measurable disease[2]	50.9	37.4	1.74* (1.23, 2.46)	0.0017
DoR, median months[1]	6.9	4.8	0.54 (0.40, 0.73)	<0.0001
Clinical benefit rate, %[3]	78.9	69.3	1.66* (1.14, 2.41)	0.0081

Survival according to Her2 status

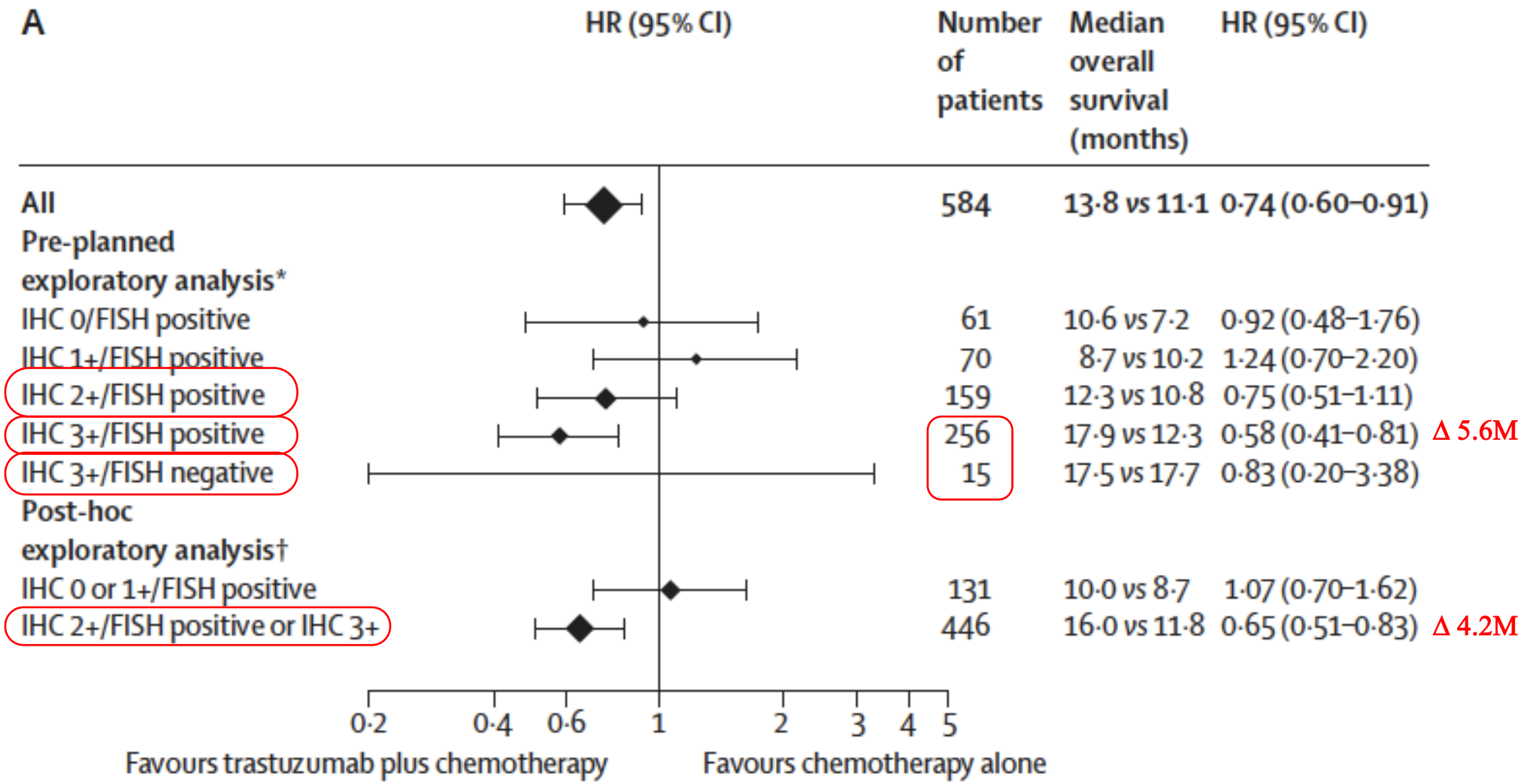
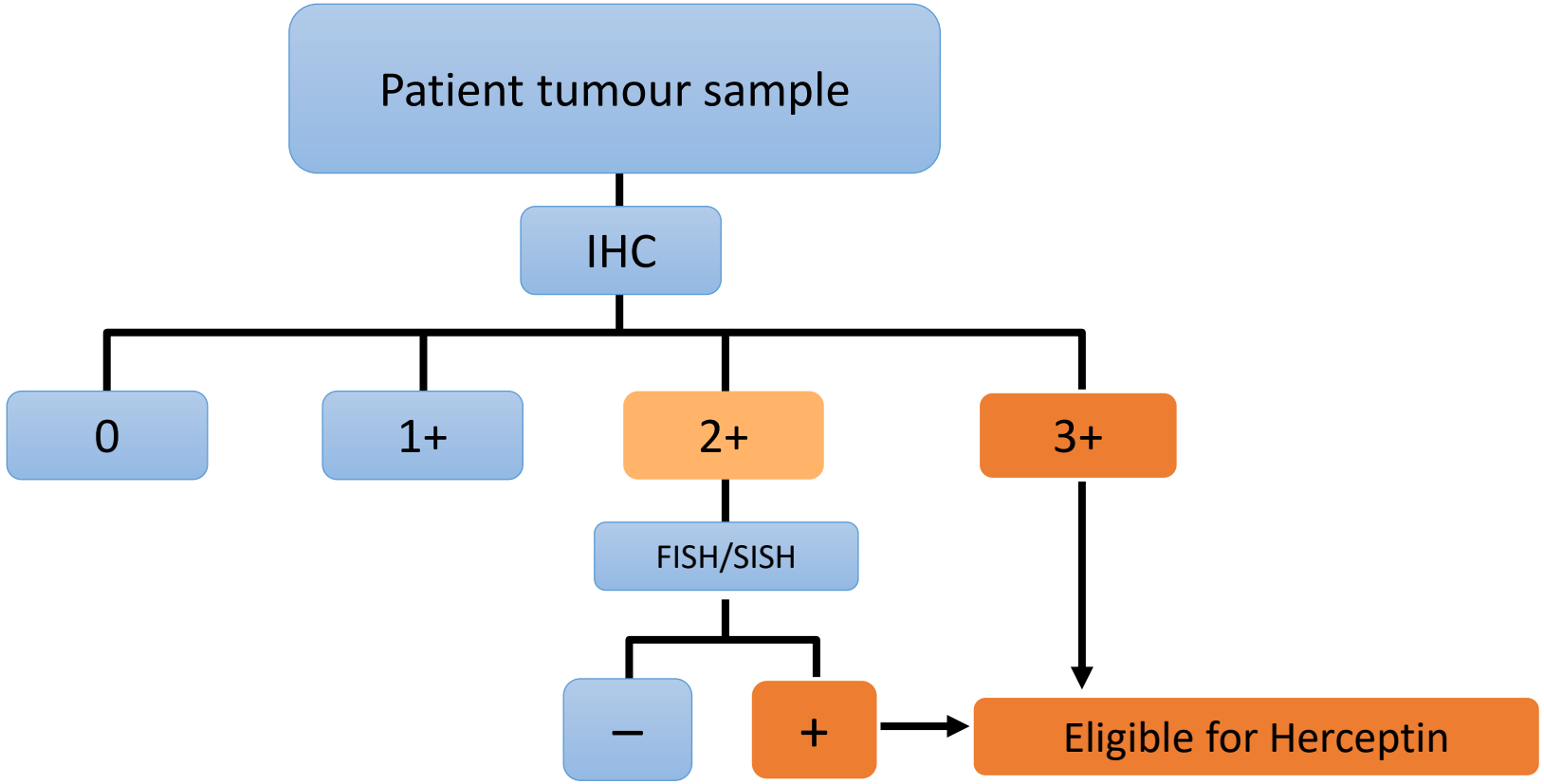


Table 1 HER2 testing results from the screening phase of the study, according to immunohistochemistry and fluorescence in situ hybridization

Total screening population[a] ($N = 3,280$)	IHC 0	IHC 1+	IHC 2+	IHC 3+	Total
FISH-positive	94[b] (4.9)	96 (15.7)	212 (54.6)	354 (94.9)	756 (23.0)
FISH-negative	1,815[b] (95.1)	514 (84.3)	176 (45.4)	19 (5.1)	2,524 (77.0)
Total	1,909 (100)	610 (100)	388 (100)	373 (100)	3,280 (100)

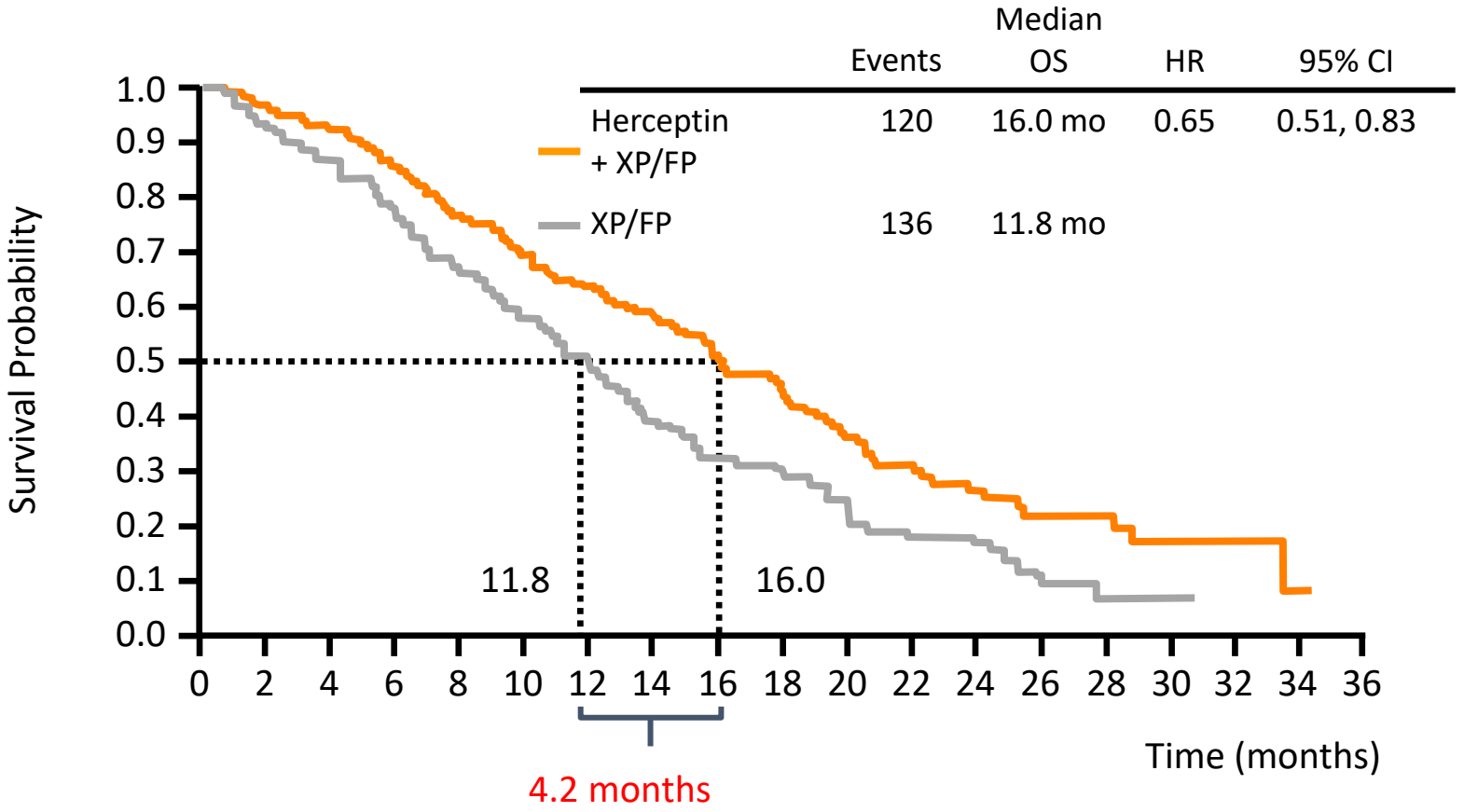
E. Van Cutsem et al. Gastric Cancer (2015) 18:476–484

Recommended HER2 testing algorithm in metastatic gastric and GE junction cancer



Dok Hyun Yoon1 & Yoon-Koo Kang Clin. Invest. (2011) 1(1), 87–95

Herceptin provides greatest OS advantage in patients with high HER2 expression level (HER2 IHC 2+/FISH+ or IHC 3+)



Bang & Van Cutsem et al 2010

Herceptin does not impact on the overall safety profile (1)

	Herceptin + XP/FP n=294		XP/FP n=290	
Adverse event, %	All grades*	Grade 3/4†	All grades*	Grade 3/4†
Nausea	67	7	63	7
Anorexia	46	6	46	6
Vomiting	50	6	46	8
Constipation	26	1	32	2
Fatigue	35	4	28	2
Diarrhoea	37	9	28	4
Hand–foot syndrome	26	1	22	2
Abdominal pain	22	2	19	2
Asthenia	19	5	18	3
Stomatitis	24	1	15	2
Weight decrease	23	2	14	2

Bang & Van Cutsem et al 2010

Herceptin does not impact on the overall safety profile (2)

	Herceptin + XP/FP n=294		XP/FP n=290	
Adverse event, %	All grades*	Grade 3/4†	All grades*	Grade 3/4†
Renal impairment	16	1	13	1
Pyrexia	18	1	12	0
Mucosal inflammation	13	2	6	1
Nasopharyngitis	13	0	6	0
Haematological AEs†				
Neutropenia	53	27	57	30
Anaemia	28	12	21	10
Thrombocytopenia	16	5	11	3

Bang & Van Cutsem et al 2010

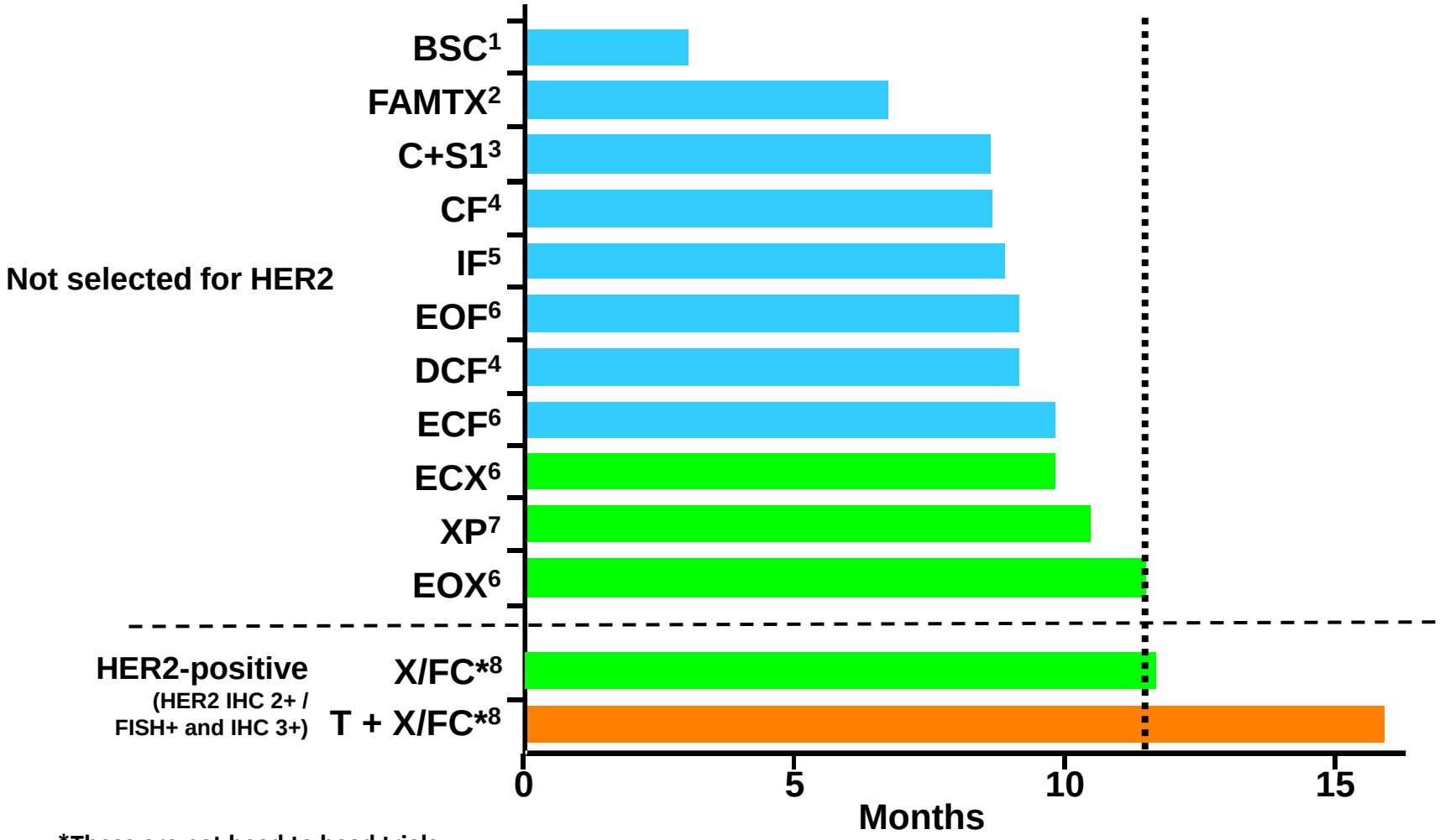
Herceptin does not impact on the cardiac safety profile

	Herceptin + XP/FP n=294		XP/FP n=290	
Cardiac adverse event, n (%)	All grades	Grade 3/4	All grades	Grade 3/4
Cardiac AEs, total	17 (6)	4 (1)	18 (6)	9 (3)
Cardiac failure	1 (<1)	1 (<1)	2 (<1)	2 (<1)
LVEF drops*				
<50%	14 (5.9)		2 (1.1)	
<50% and by ≥10%	11 (4.6)		2 (1.1)	
Cardiac AEs leading to death	2 (<1) Acute MI; cardiac failure		2 (<1) Cardiac arrest; cardio-respiratory arrest	

*Measured at baseline and every 12 weeks; MI, myocardial infarction

Bang & Van Cutsem et al 2010

Herceptin has the major impact on OS in HER2 positive gastric cancer



*These are not head to head trials.

1. Murad, et al. Cancer 1993; 2. Vanhoefer, et al. JCO 2000; 3. Ajani, et al. ASCO GI 2009; 4. Van Cutsem, et al. JCO 2006
5. Dank, et al. Ann Oncol 2008; 6. Cunningham, et al. NEJM 2008; 7. Kang, et al. Ann Oncol 2009; 8. Van Cutsem, et al. JCO 2009
*87.1% patients received Xeloda; T = Herceptin

TFDA indication

- 轉移性胃癌(mGC) Herceptin合併capecitabine (或5-fluorouracil)及cisplatin適用於未曾接受過化學治 療之HER2過度表現轉移性胃腺癌(或胃食道接合處腺癌)的治療。
- 說明：
- (1) HER2過度表現之檢測方法須經衛生主管機關核准(用於胃癌之檢驗)，請 參照相關檢測套組仿單中適應症，確效(validation)及效能(performance)之 敘述。另請參照本仿單[轉移性胃癌(12.3)]之敘述。
- (2) 樞紐試驗確認療效僅顯現於有較高HER2蛋白表現(IHC2+/FISH+或IHC3+)之族群。HER2次族群分析結果顯示，HER2蛋白表現較低(IHC 0/FISH+: HR 0.92; IHC 1+/FISH+: HR 1.24)的族群的療效總體提升不高， 反之，HER2蛋白表現較高(IHC 2+/FISH+: HR 0.75; IHC 3+/FISH+: HR 0.58)的族群的療效總體提升較高。

Outlines

- HER2 and ToGA trial in gastric cancer
- Real world experience
- Case sharing

Turkey
(n=35)

Journal of Gastrointestinal Cancer
https://doi.org/10.1007/s12029-021-00594-1

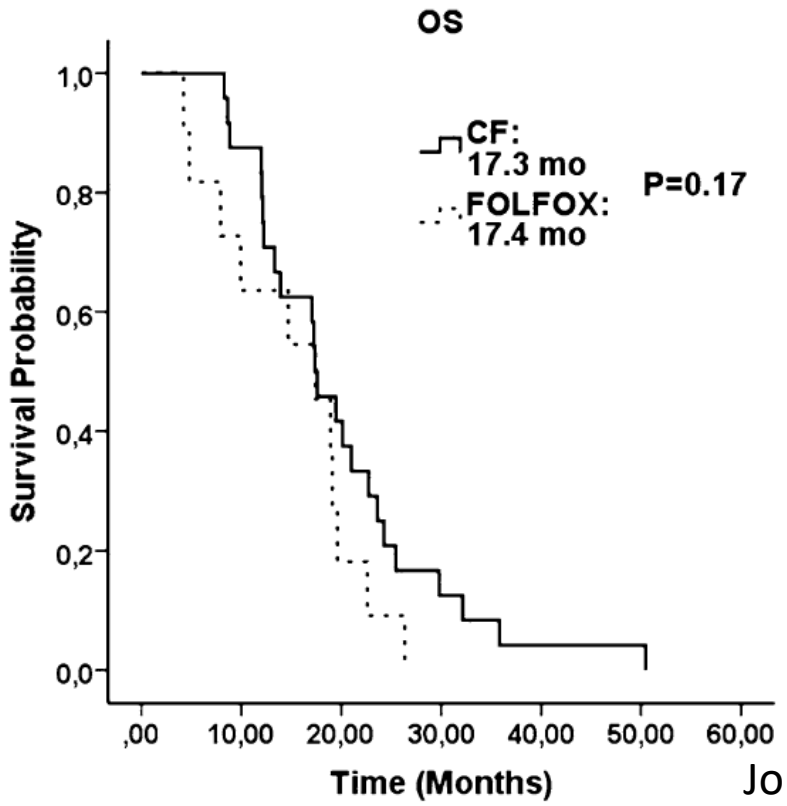
ORIGINAL RESEARCH

Trastuzumab ± Capecitabine Maintenance After the First-Line Treatment of HER2-Positive Advanced Gastric Cancer: Retrospective Observational Real-Life Data of Turkish Oncology Group

Mustafa Gürbüz[1] · Erman Akkuş[2] · Abdullah Sakin[3] · Semiha Urvay[4] · Atike Gökçen Demiray[5] · Süleyman Şahin[6] · Teoman Şakalar[7] · Cihan Erol[8] · Mehmet Ali Nahit Şendur[8] · Ahmet Bilgehan Şahin[9] · Erdem Çubukçu[9] · Deniz Can Güven[10] · Saadettin Kılıçkap[10] · Yakup Ergün[11] · Doğan Uncu[11] · Nazım Serdar Turhal[12] · Necdet Üskent[12] · Havva Yeşil Çınkır[13] · Atakan Demir[14] · Ramazan Acar[15] · Nuri Karadurmuş[15] · Sema Türker[16] · Mustafa Altınbaş[16] · Mert Karaoğlan[2] · Filiz Çay Şenler[1]

Accepted: 24 January 2021

PFS 12 months / OS 17.4 months



Journal of Gastrointestinal Cancer, 2021

Korea
(n=47)

RESEARCH ARTICLE Open Access

Trastuzumab-based palliative chemotherapy for HER2-positive gastric cancer: a single-center real-world data

Tae-Hwan Kim[1], Hun Do Cho[1], Yong Won Choi[1], Hyun Woo Lee[1], Seok Yun Kang[1], Geum Sook Jeong[1], Jin-Hyuk Choi[1*†], Mi Sun Ahn[1*†] and Seung-Soo Sheen[2]

PFS 6.9 months / OS 12.8 months

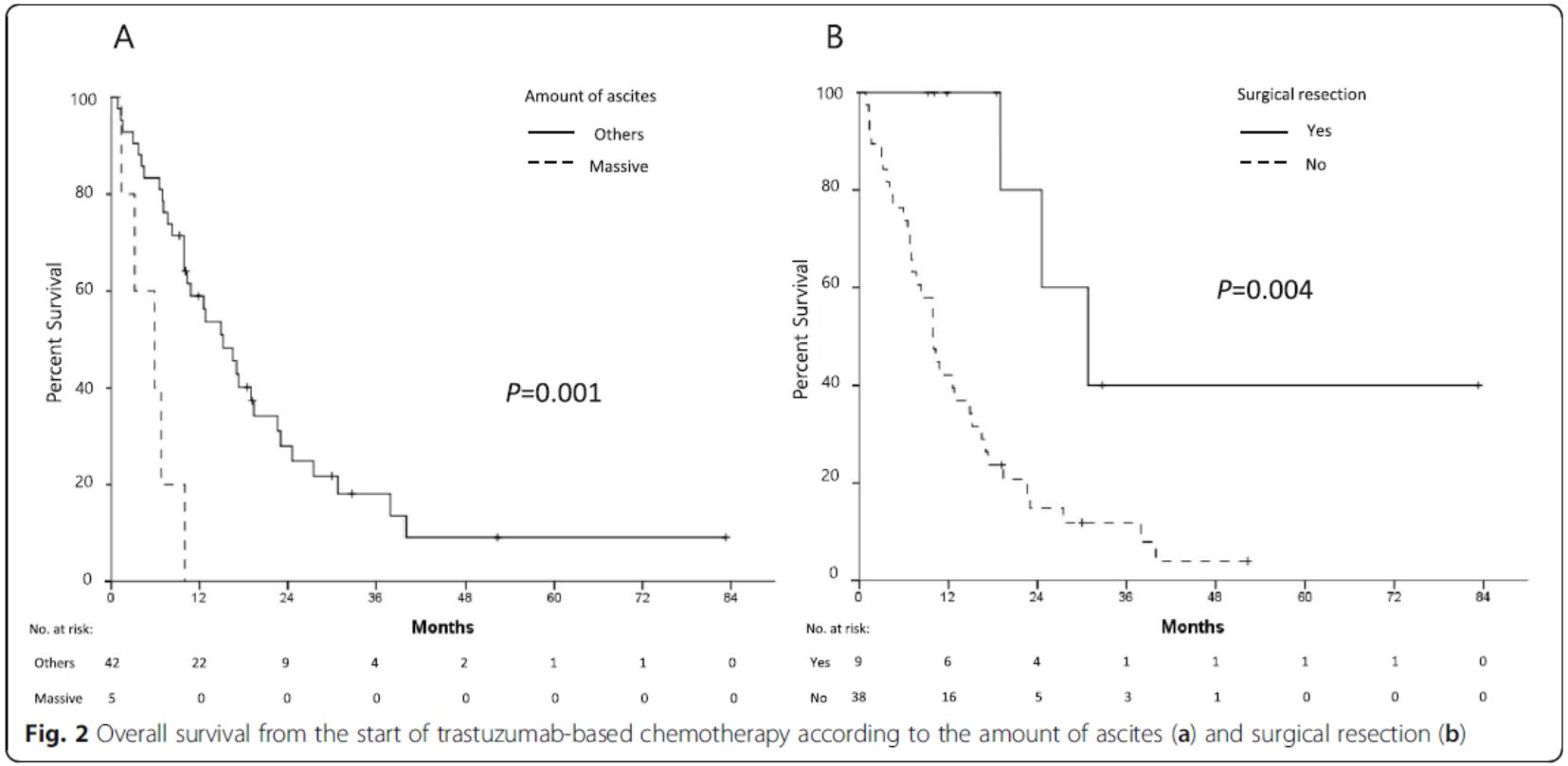


Fig. 2 Overall survival from the start of trastuzumab-based chemotherapy according to the amount of ascites (**a**) and surgical resection (**b**)

Kim et al. BMC Cancer (2021) 21:325

Germany (n=364)

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Gastrointestinal Cancer

Clinical Practice Observation of Trastuzumab in Patients with Human Epidermal Growth Receptor 2-Positive Metastatic Adenocarcinoma of the Stomach or Gastroesophageal Junction

Table 1. Subgroups of patients by type of chemotherapy regimen: AP

Subgroup by type of chemotherapy	Combination of cancer drugs	No. of patients within the AP
In-Label	Trastuzumab +5-FU or capecitabine + cisplatin (+ other drugs)	172
FLOT[a]	Trastuzumab +5-FU + docetaxel + oxaliplatin (+leucovorin)[b]	37
Fluoropyrimidine	Trastuzumab +5-FU or capecitabine (+leucovorin)[b]	33
Oxaliplatin / Fluoropyrimidine	Trastuzumab +5-FU + oxaliplatin (+leucovorin)[b]	70
Other regimens	All other trastuzumab -containing combinations	52

Table 3. ORR: AP and marginal HER2-positivity population

Population or subgroup	*n*	ORR[a] (patients)	95% CI for response rates
AP	364	43.4% (158)	38%–49%
Subgroups of AP by chemotherapy:			
In-Label	172	41.9% (72)	34%–50%
FLOT	37	54.1% (20)	37%–71%
Fluoropyrimidine	33	39.4% (13)	23%–58%
Oxaliplatin/ Fluoropyrimidine	70	48.6% (34)	36%–61%
Other regimens	52	36.5% (19)	24%–51%
Marginal HER2-positivity population	39	43.6% (17)	28%–60%

Germany
(n=364)

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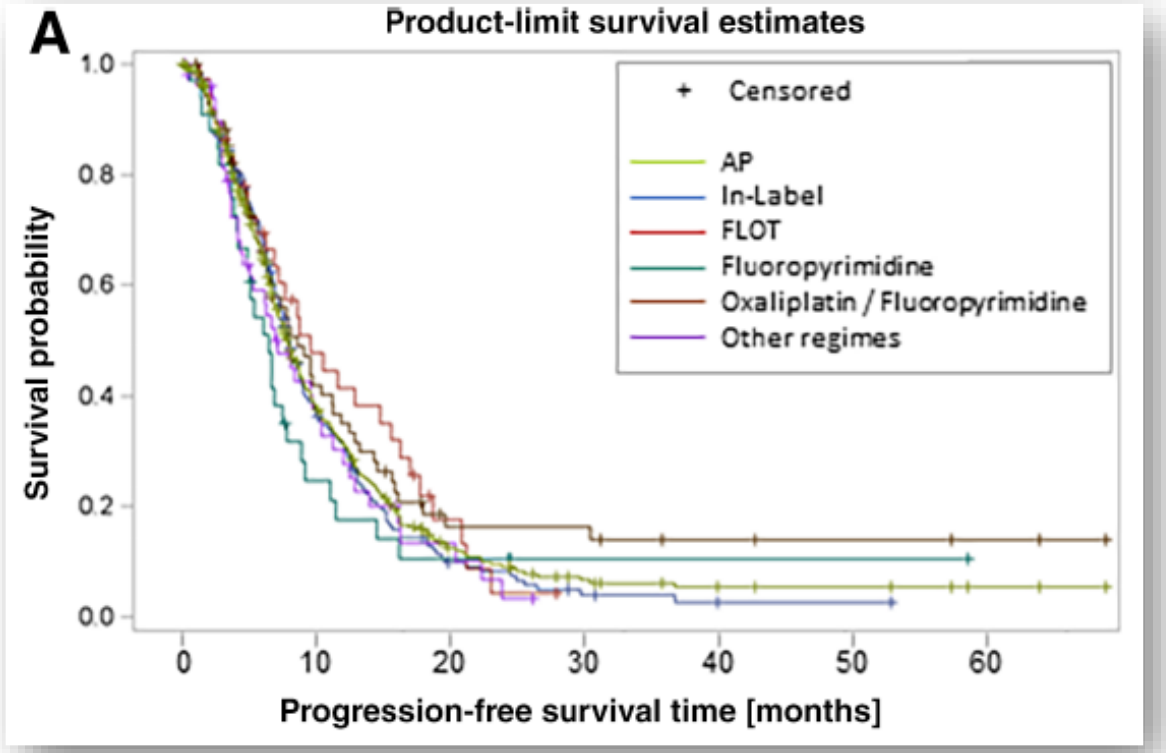
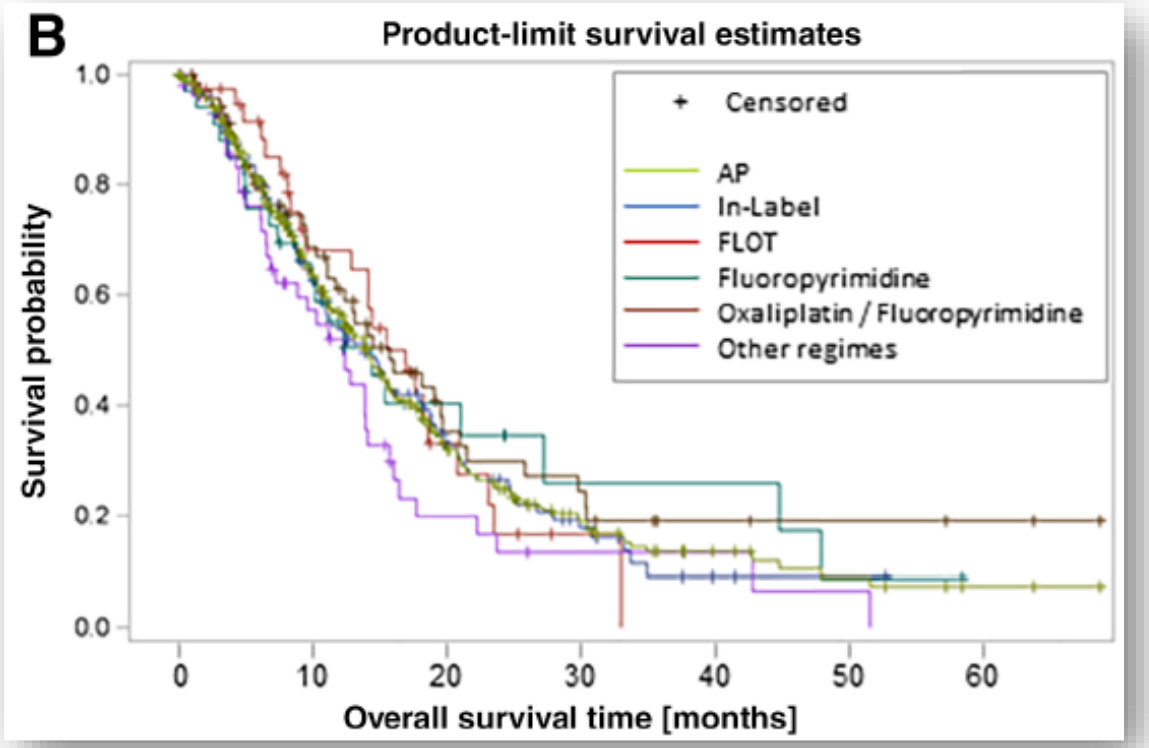
Gastrointestinal Cancer

Clinical Practice Observation of Trastuzumab in Patients with Human Epidermal Growth Receptor 2-Positive Metastatic Adenocarcinoma of the Stomach or Gastroesophageal Junction



7.9 months



14.1 months

Canada (n=476)

Contents lists available at ScienceDirect

Clinical Oncology

journal homepage: www.clinicaloncologyonline.net

Original Article

Effectiveness of Trastuzumab in Routine Clinical Practice: A Population-based Study of Patients with HER-2-positive Oesophageal, Gastroesophageal and Gastric Cancer

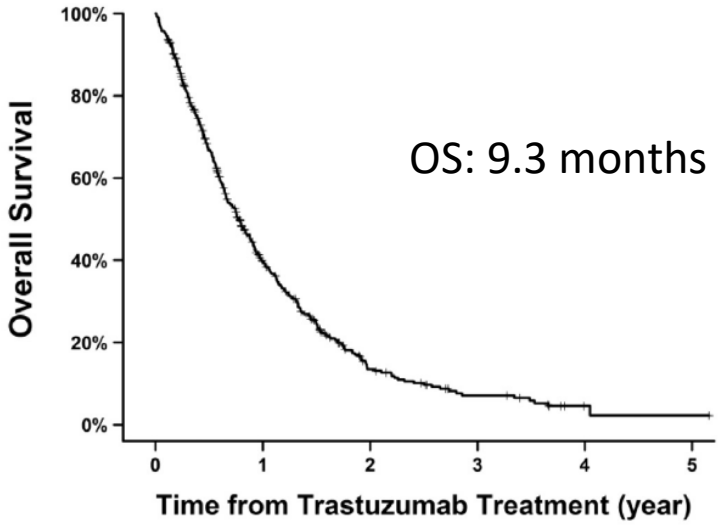
S.J. Merchant *, W. Kong †, B. Gyawali †, T. Hanna †, W. Chung *, S. Nanji *, S.V. Patel *, C.M. Booth †

* *Department of Surgery, Queen's University, Kingston, Ontario, Canada*
† *Division of Cancer Care and Epidemiology, Queen's Cancer Research Institute, Kingston, Ontario, Canada*

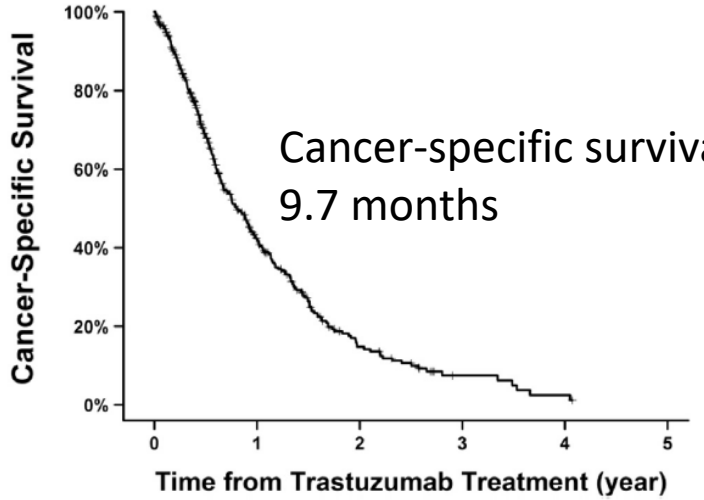
Received 27 November 2019; received in revised form 16 June 2020; accepted 15 July 2020

Table 2
Chemotherapeutic agents used in conjunction with trastuzumab*

Chemotherapy agents	*n* (%)
Capecitabine	213 (45%)
Carboplatin	61 (13%)
Cisplatin	373 (78%)
Fluorouracil	164 (35%)
Other†	7 (2%)



OS: 9.3 months



Cancer-specific survival 9.7 months

Clinical Oncology, 2021

China (n=11)

OncoTargets and Therapy

Dovepress
open access to scientific and medical research

Open Access Full Text Article

ORIGINAL RESEARCH

Efficacy and safety of trastuzumab as maintenance or palliative therapy in advanced HER2-positive gastric cancer

Results: The overall response rate (ORR) was 9.10%, and the disease control rate (DCR) was 63.64%. The median overall survival (OS) was 6.10 months, and the median progression-free survival (PFS) was 6.10 months. A significant association was found between trastuzumab treatment cycles and efficacy (P=0.027), cycles and PFS (P=0.001), and cycles and OS (P=0.005).

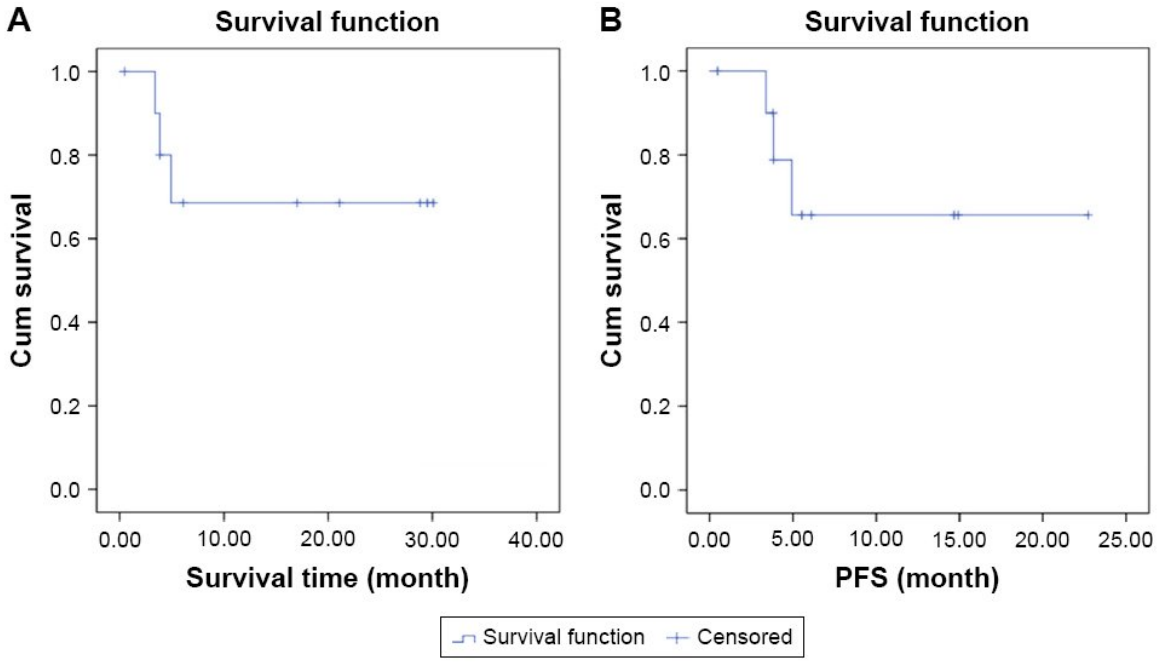
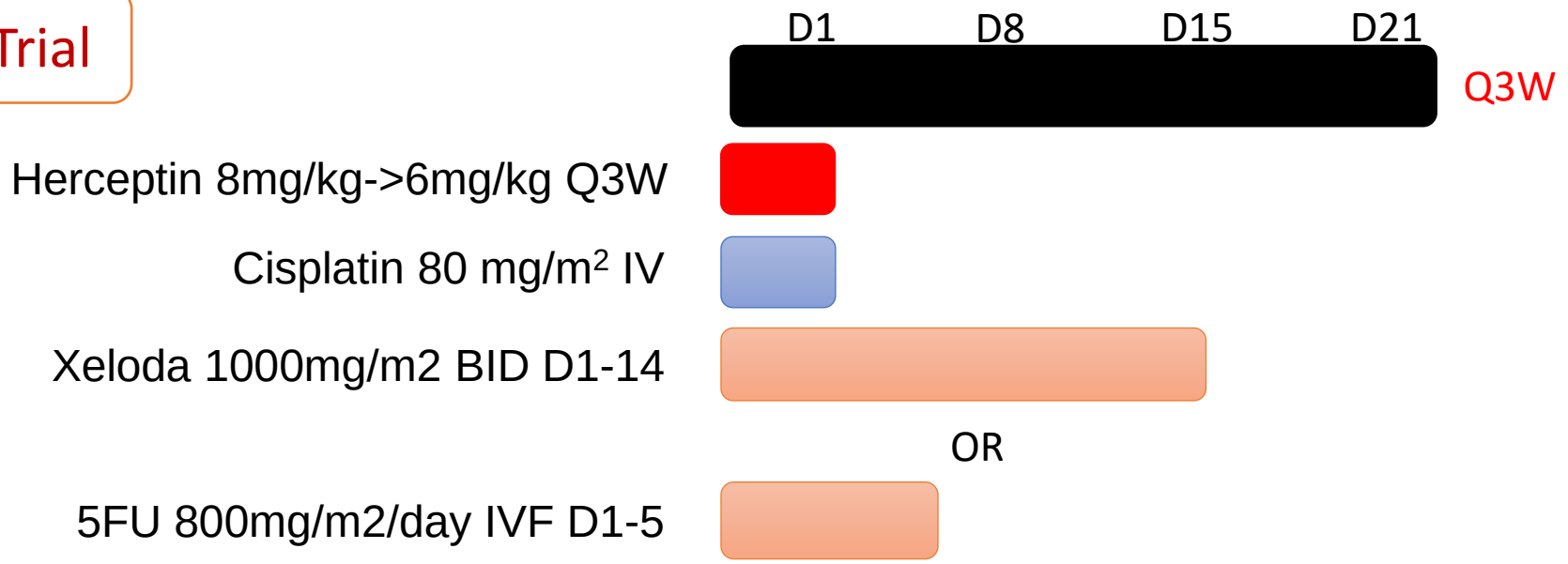


Figure 3 The Kaplan–Meier curves of OS (**A**) and PFS (**B**) for all 11 patients.
Abbreviations: Cum, Cumulative; OS, overall survival; PFS, progression-free survival.

ToGA Trial



Cisplatin → Oxaliplatin ?

Effectiveness and safety of oxaliplatin compared to cisplatin for advanced, unresectable gastric cancer: a systematic review and meta-analysis

Francesco Montagnani · Gina Turrisi · Claudio Marinozzi · Camillo Aliberti · Giammaria Fiorentini

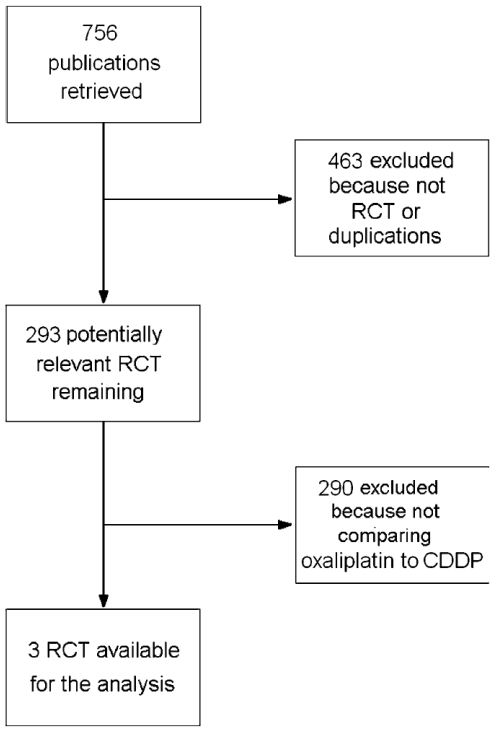
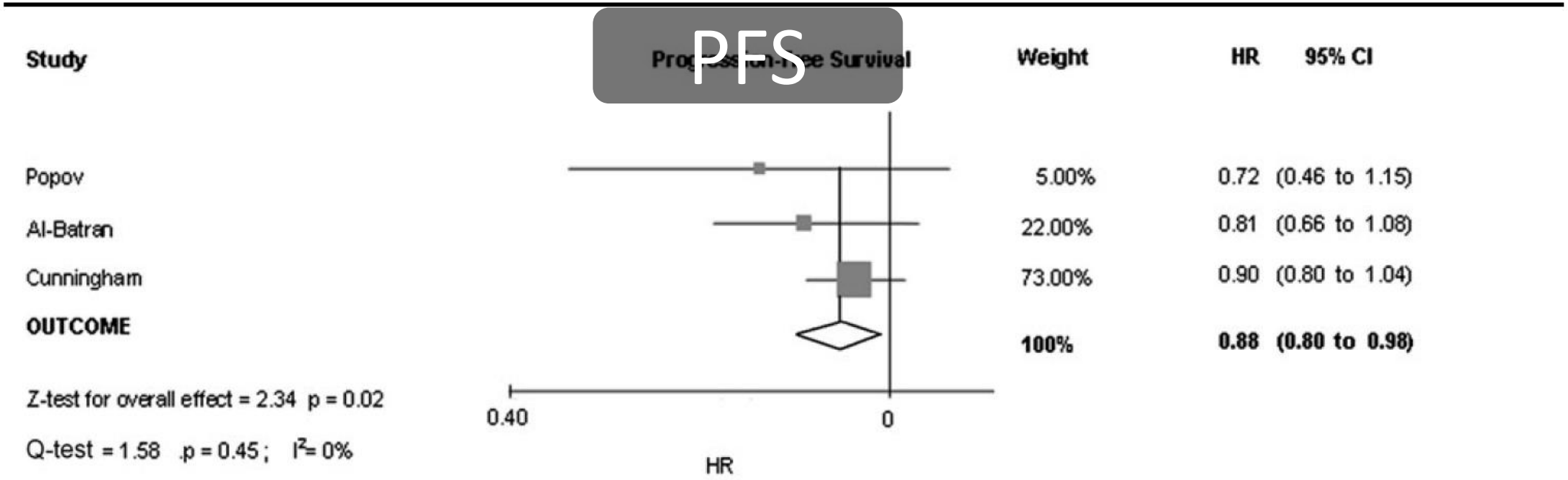


Table 1 Study characteristics

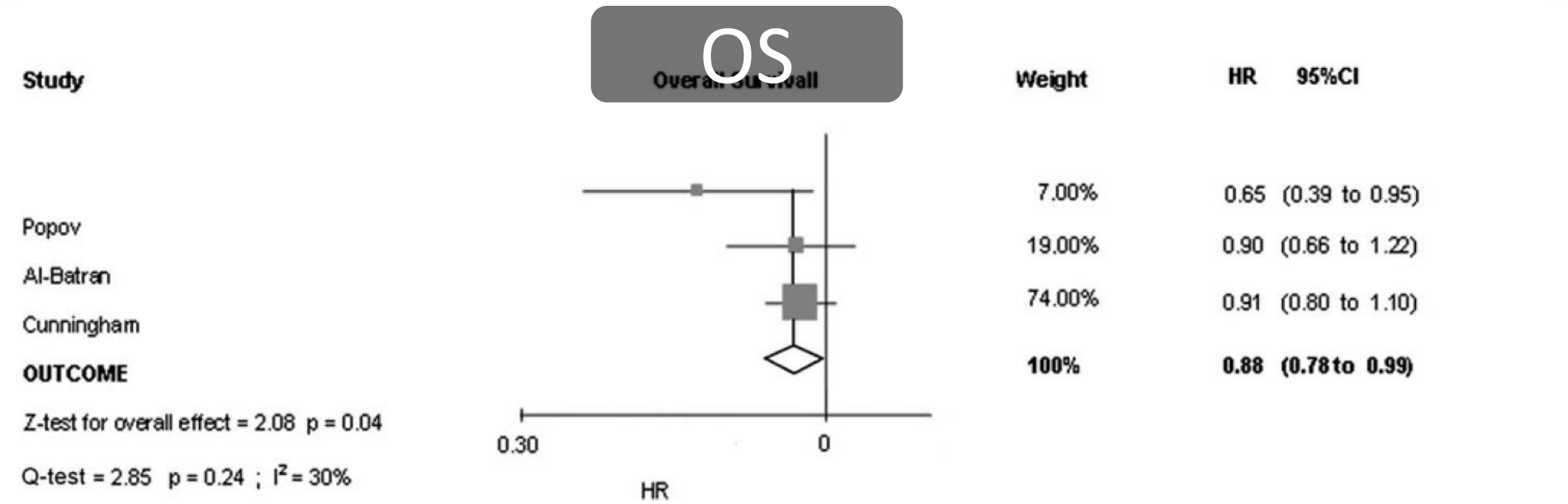
Study (references)	Patients (*N*)	Treatment	Patient population	Jadad score
Cunningham et al. [12] phase III	1002	ECF[a] = epirubicin 60 mg/m^2 d1, cisplatin 50 mg/m^2 d1, 5-FU c.i. 200 mg/m^2 ECX[a] = epirubicin 50 mg/m^2 d1, cisplatin 50 mg/m^2 d1, capecitabine 625 mg/m^2 × 2 daily EOF[a] = epirubicin 60 mg/m^2 d1, oxaliplatin 85 mg/m^2 d1, 5-FU c.i. 200 mg/m^2 daily EOX[a] = epirubicin 60 mg/m^2 d1, oxaliplatin 85 mg/m^2 d1, capecitabine 625 mg/m^2 × 2 daily	Unresectable locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma.	3
Al-Batran et al. [14] Phase II	220	FLO[b] = oxaliplatin 85 mg/m^2 d1, 5-FU 2600 mg/m^2 24 h-c.i. d1, FA 200 mg/m^2 d1 FLP[b] = cisplatin 50 mg/m^2 d1, 5-FU 2000 mg/m^2 24 h c.i. d1, FA = 200 mg/m^2 d1	Unresectable locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma.	2
Popov et al. [15] Phase II	62	Arm1[b] = oxaliplatin 85 mg/m^2 d1, 5-FU bolus 400 mg/m^2 d1, 2, 5-FU 600 mg/m^2 22 h c.i. d1, 2, FA = 200 mg/m^2 d1, 2 Arm 2[b] = cisplatin 50 mg/m^2 d1,5-FU bolus 400 mg/m^2 d1, 2, 5-FU 600 mg/m^2 22 h c.i. d1, 2, FA = 200 mg/m^2 d1, 2	Unresectable locally advanced or metastatic gastric adenocarcinoma.	2

Gastric Cancer (2011) 14:50–55

PFS


Study
Progression-Free Survival
Weight
HR
95% CI
Popov
5.00%
0.72 (0.46 to 1.15)
Al-Batran
22.00%
0.81 (0.66 to 1.08)
Cunningham
73.00%
0.90 (0.80 to 1.04)
OUTCOME
100%
0.88 (0.80 to 0.98)
Z-test for overall effect = 2.34 p = 0.02
Q-test = 1.58 p = 0.45 ; I² = 0%
0.40
0
HR

OS


Study
Overall Survival
Weight
HR
95%CI
Popov
7.00%
0.65 (0.39 to 0.95)
Al-Batran
19.00%
0.90 (0.66 to 1.22)
Cunningham
74.00%
0.91 (0.80 to 1.10)
OUTCOME
100%
0.88 (0.78 to 0.99)
Z-test for overall effect = 2.08 p = 0.04
Q-test = 2.85 p = 0.24 ; I² = 30%
0.30
0
HR

Multicenter phase II study of trastuzumab in combination with capecitabine and oxaliplatin for advanced gastric cancer

Min-Hee Ryu [a,1], Changhoon Yoo [a,1], Jong Gwang Kim [c], Baek-Yeol Ryoo [a], Young Soo Park [b], Sook Ryun Park [a], Hye-Suk Han [d], Ik Joo Chung [e], Eun-Kee Song [f], Kyung Hee Lee [g], Seok Yun Kang [h], Yoon-Koo Kang [a,*]

European Journal of Cancer (2015) 51, 482– 488

Phase II study to evaluate the efficacy of Trastuzumab in combination with Capecitabine and Oxaliplatin in first-line treatment of HER2-positive advanced gastric cancer: HERXO trial

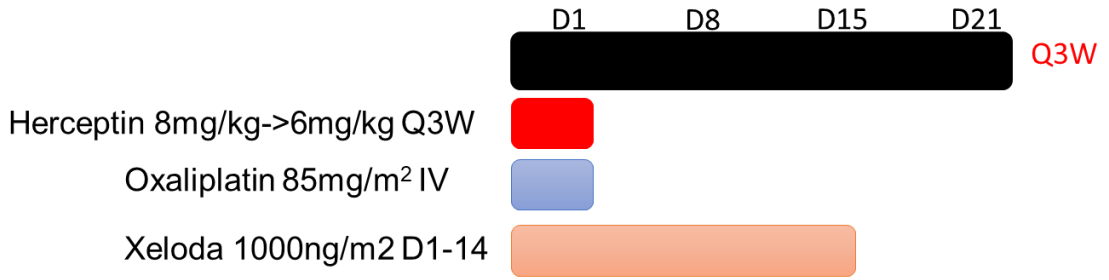
Fernando Rivera[1] · C. Romero[2] · P. Jimenez-Fonseca[3] · M. Izquierdo-Manuel[3] · A. Salud[4] · E. Martínez[1] · M. Jorge[5] · V. Arrazubi[6] · J. C. Méndez[7] · P. García-Alfonso[8] · M. Reboredo[9] · J. Barriuso[10] · N. Muñoz-Unceta[1] · R. Jimeno[1] · C. López[1]

Cancer Chemotherapy and Pharmacology (2019) 83:11

RESEARCH ARTICLE Open Access

Optimal regimen of trastuzumab in combination with oxaliplatin/ capecitabine in first-line treatment of HER2-positive advanced gastric cancer (CGOG1001): a multicenter, phase II trial

Jifang Gong[1†], Tianshu Liu[2†], Qingxia Fan[3], Li Bai[4], Feng Bi[5], Shukui Qin[6], Jinwan Wang[7], Nong Xu[8], Ying Cheng[9], Yuxian Bai[10], Wei Liu[11], Liwei Wang[12] and Lin Shen[1*]



Gongetal.BMC Cancer (2016) 16:68

Cisplatin vs Oxaliplatin

	Cisplatin	Oxaliplatin		
	ToGA Trial 2010 n=294	Ryu MH, et al. 2015 n=57	Rivera F, et al. 2019 n=45	Gong J, et al. 2016 n=51
ORR	47%	67%	46.7%	66.7%
PFS	6.7 months	9.8 months	7.1 months	9.2 months
OS	13.8 months	21 months	13.8 months	19.5 months

ToGa Trial, Bang, et al. 2010 Lancet
Ryu MH, et al. 2015 Eur J Cancer
Rivera F, et al. 2019 Cancer Chemother Pharmacol
Gong J, et al. 2016 BMC Cancer

PRINCIPLES OF SYSTEMIC THERAPY

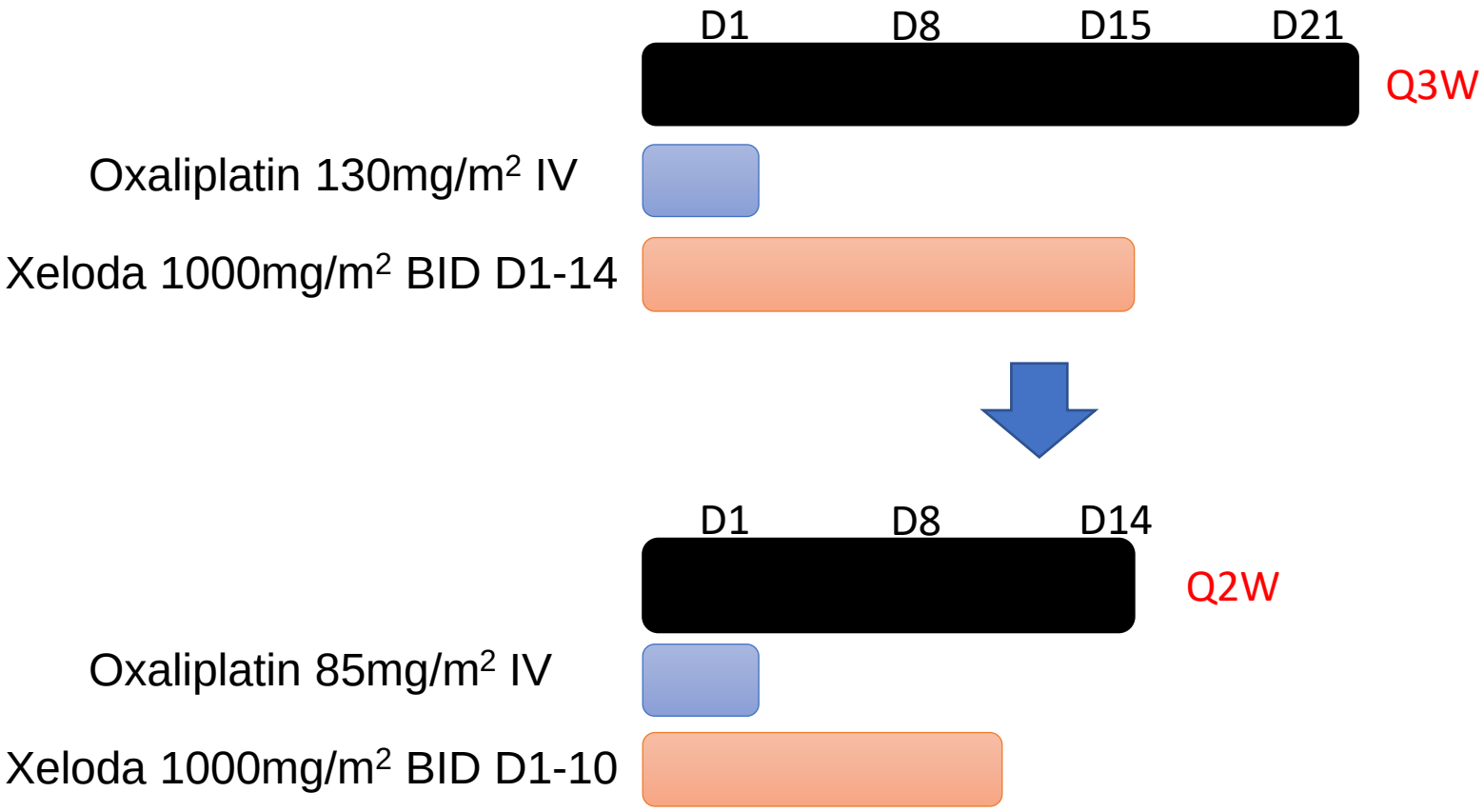
Systemic Therapy for Unresectable Locally Advanced, Recurrent or Metastatic Disease (where local therapy is not indicated)

First-Line Therapy
- Oxaliplatin is generally preferred over cisplatin due to lower toxicity.

Preferred Regimens
- HER2 overexpression positive adenocarcinoma[f]
  - Fluoropyrimidine (fluorouracil[b] or capecitabine) and oxaliplatin and trastuzumab[a]
  - Fluoropyrimidine (fluorouracil[b] or capecitabine) and cisplatin and trastuzumab (category 1)[a,11]
- HER2 overexpression negative[f]
  - Fluoropyrimidine (fluorouracil[b] or capecitabine), oxaliplatin, and nivolumab (PD-L1 CPS ≥5) (category 1)[g,h,12]
  - Fluoropyrimidine (fluorouracil[b] or capecitabine) and oxaliplatin[13-15]
  - Fluoropyrimidine (fluorouracil[b] or capecitabine) and cisplatin[13,16-18]

Other Recommended Regimens
(trastuzumab[a] should be added to first-line chemotherapy for HER2 overexpression positive adenocarcinoma)
- Fluorouracil[b,i] and irinotecan[19]
- Paclitaxel with or without cisplatin or carboplatin[20-24]
- Docetaxel with or without cisplatin[25-28]
- Fluoropyrimidine[17,29,30] (fluorouracil[b] or capecitabine)
- Docetaxel, cisplatin or oxaliplatin, and fluorouracil[b,31,32]
- Docetaxel, carboplatin, and fluorouracil (category 2B)[33]

CGMH experience



Modified Biweekly Oxaliplatin and Capecitabine for Advanced Gastric Cancer: A Retrospective Analysis from A Medical Center

Yung-Chia Kuo[1], Hao-Tien Liu[2], Yi-Lun Lin[2], Yi-Chun Yang[2], Tsai-Sheng Yang[1], Chi-Ting Liau[1], Wen-Chi Shen[1]. Hung-Chih Hsu[1], Wen-Chi Chou[1], Jen-Shi Chen[1,2]

Table 1: Patient characteristics, *n*=49

Characteristics	Number of patients (%)
Age, median	59
Range	28-77
Gender	
Male	28 (57)
Female	21 (43)
Performance status (ECOG)	
0	21 (42.9)
1	24 (49.0)
≥2	4 (8.1)
Stage	
2	3 (6.1)
3	6 (12.2)
4	40 (81.7)
Gastrectomy or bypass surgery	
No	40
Yes	9
Evaluated for response	46
Not assessed	3

Abbreviation: ECOG: Eastern cooperative oncology group

Table 2: The reasons for off-treatment of mXELOX regimen

	No. of patients (%)
Toxicity	22 (44)
Neuropathy	7 (14)
GI symptoms	5 (10)
Leukopenia	1 (2)
Thrombocytopenia	2 (4)
Hand foot syndrome	2 (4)
Infection (including mortality*)	4 (8)*
Allergy	1 (2)
Disease progression	19 (34)
Physician decision	4 (8)
Transfer or loss to follow-up/patient refusal	4 (8)

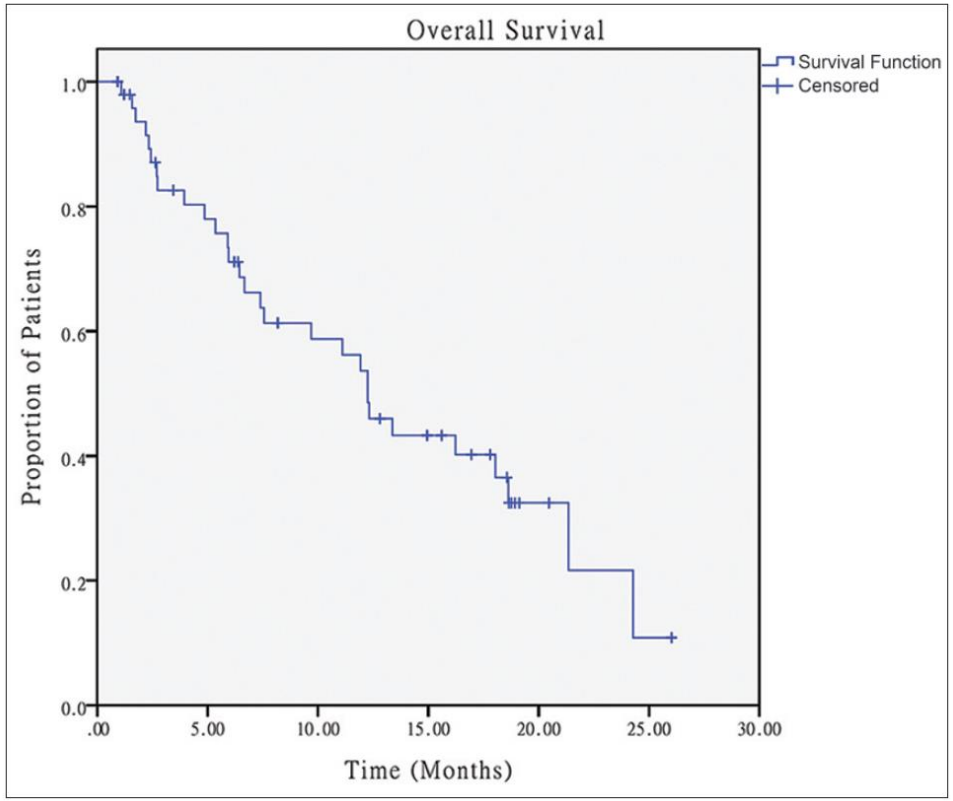
*Three patients died of infection (6%), all were cancer related, none related to bone marrow toxicity. Abbreviation: mXELOX: modified XELOX

Response and Survival

Table 4: Efficacy and survival of mXELOX regime, *n*=46

	No. of patients (%)
Response rate	18 (39.13)
Complete response	3 (6.52)
Partial response	15 (32.61)
Stable disease	7 (15.22)
Progressive disease	21 (45.65)
Median time to disease progression	4.35 months (95% CI 1.54-7.16)
Median overall survival	12.03 months (95% CI 9.68-14.38)

Abbreviations: mXELOX: modified XELOX; CI: Confidence interval



Biomed J Vol. 37 No. 3 May - June 2014

Outlines

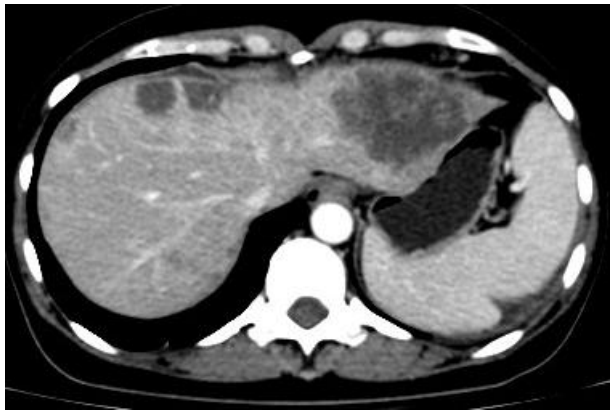
- HER2 and ToGA trial in gastric cancer
- Real world experience
- Case sharing

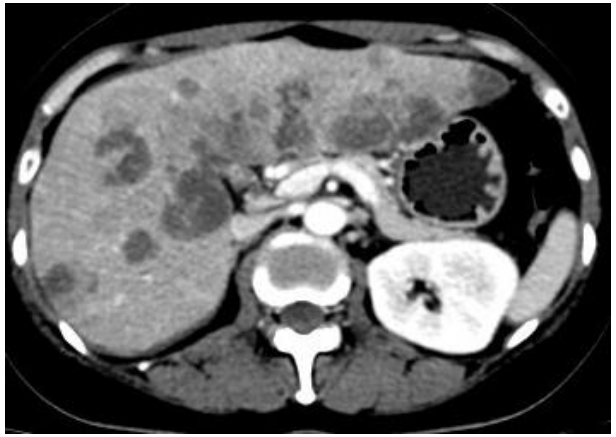
Case Sharing -1

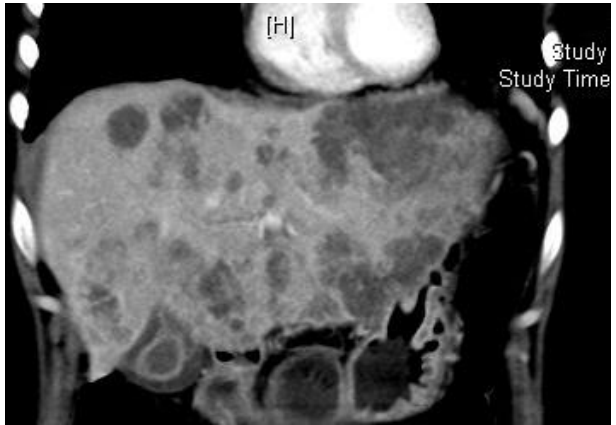
- 2012/09

- 45F, to ER, gastric cancer, stage IV, HER-2: 3+

2012/9





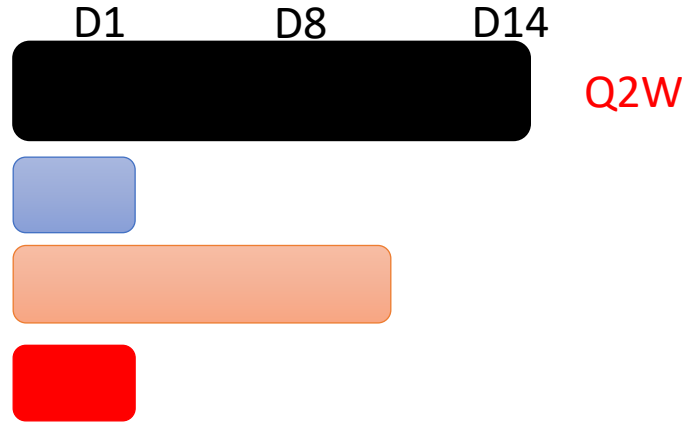


45F, gastric cancer, stage IV, HER-2: 3+

Bilirubin: 2.0

Pain control for severe abdominal pain

PS: 2-3



Oxaliplatin 85mg/m^2 IV

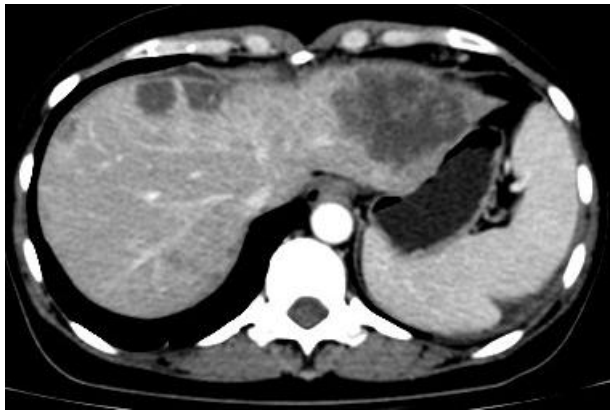
Xeloda 1000mg/m2 BID D1-10

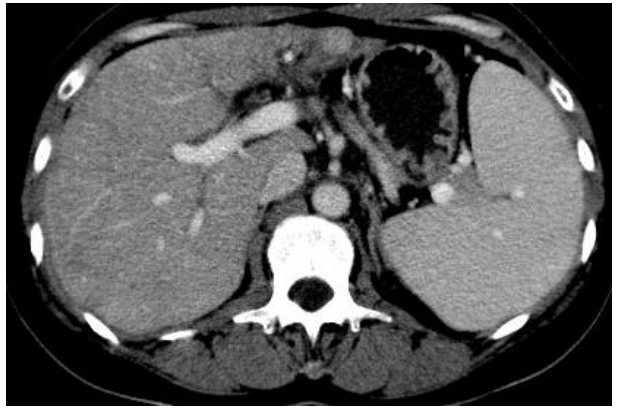
Herceptin 8mg/kg->4mg/kg Q2W

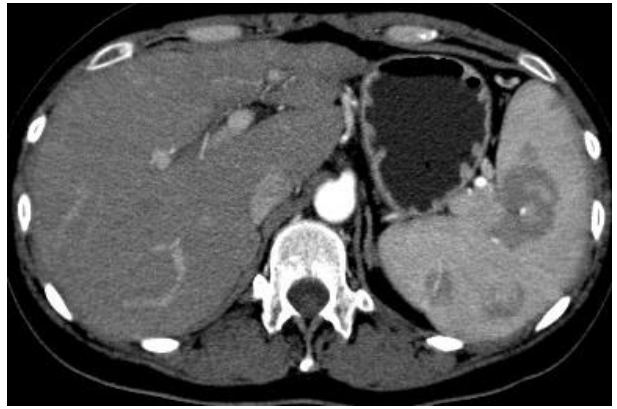
2012/9

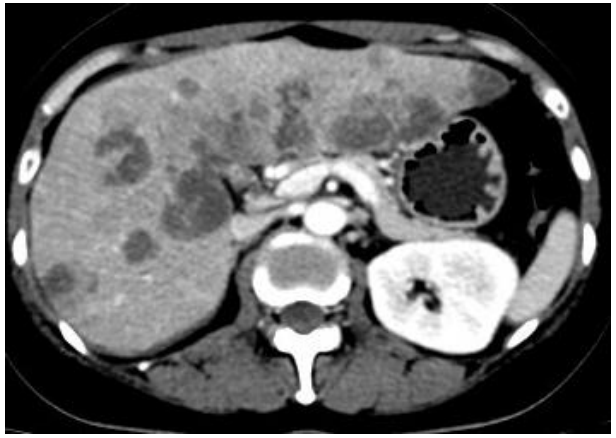
2012/12

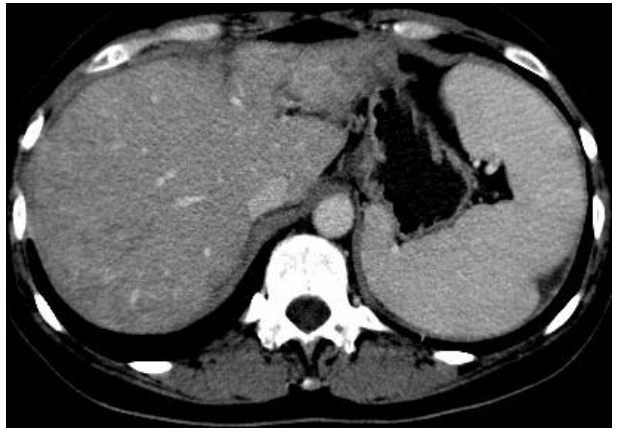
2013/03

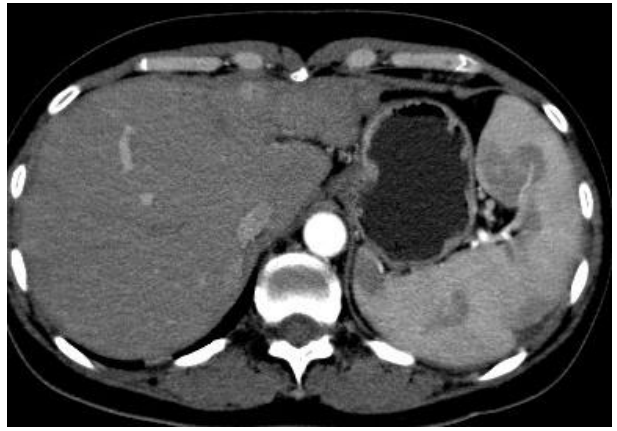


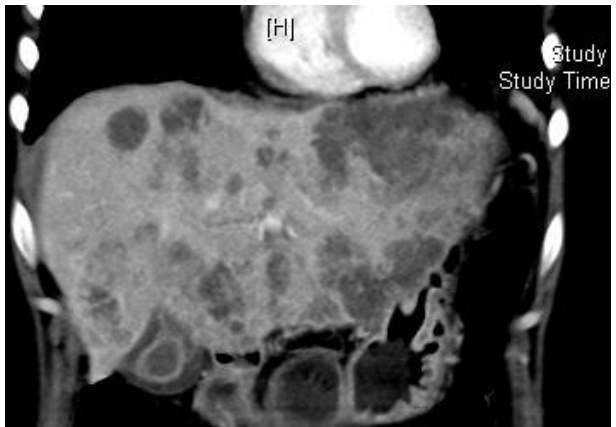


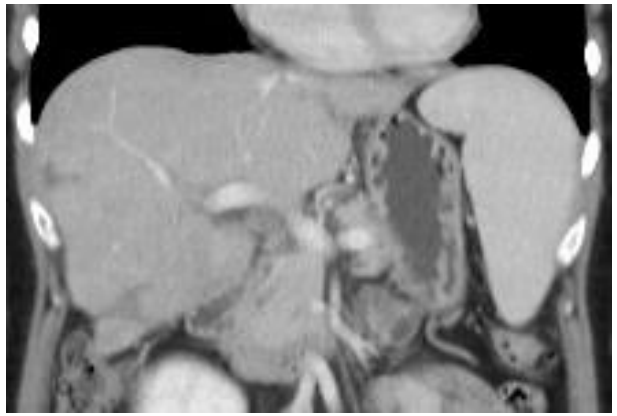


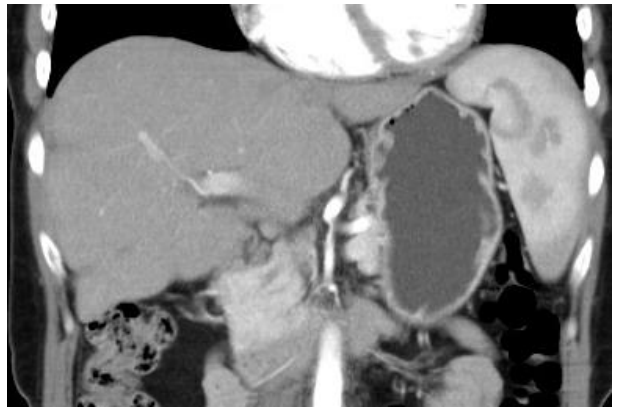




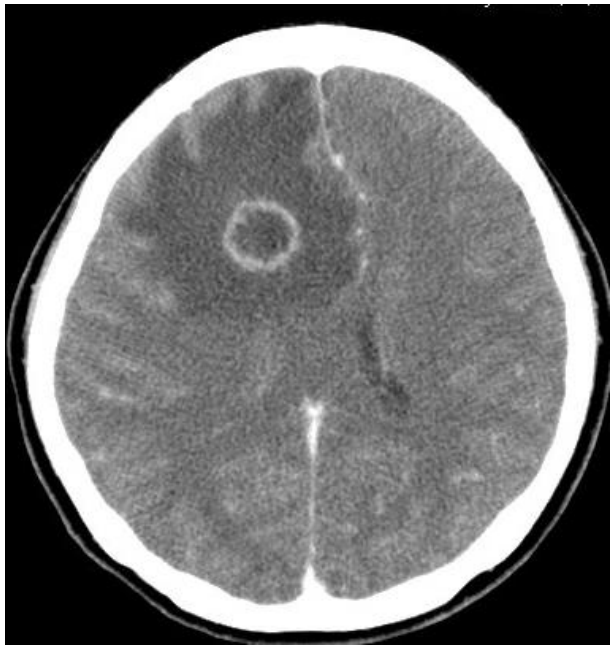




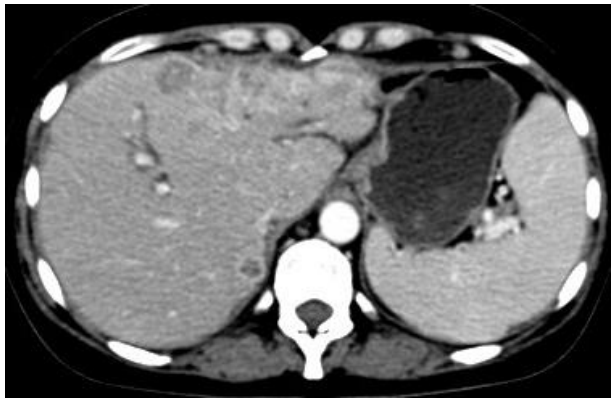


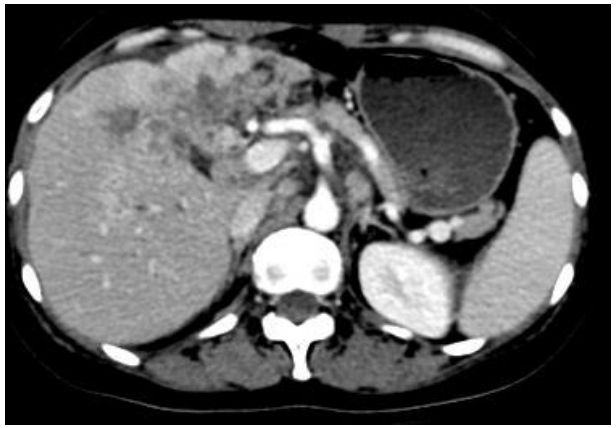


2013/4

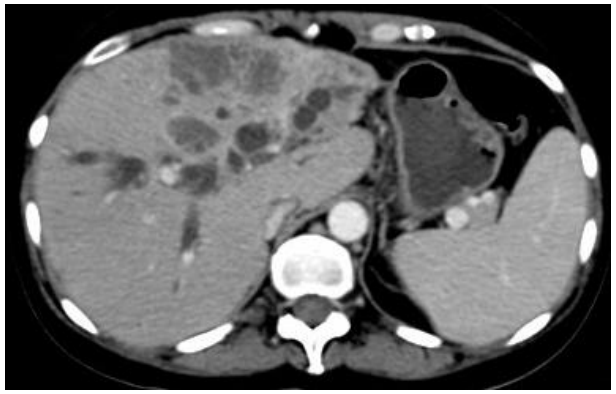


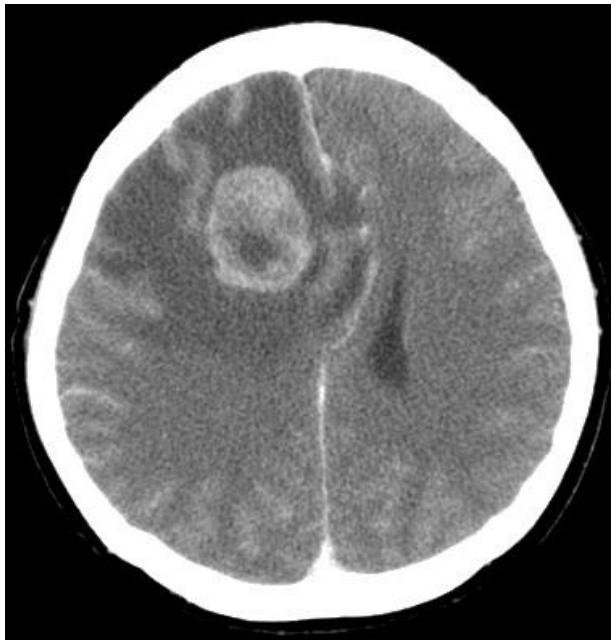
2013/5





2013/6





2013/10
Expired

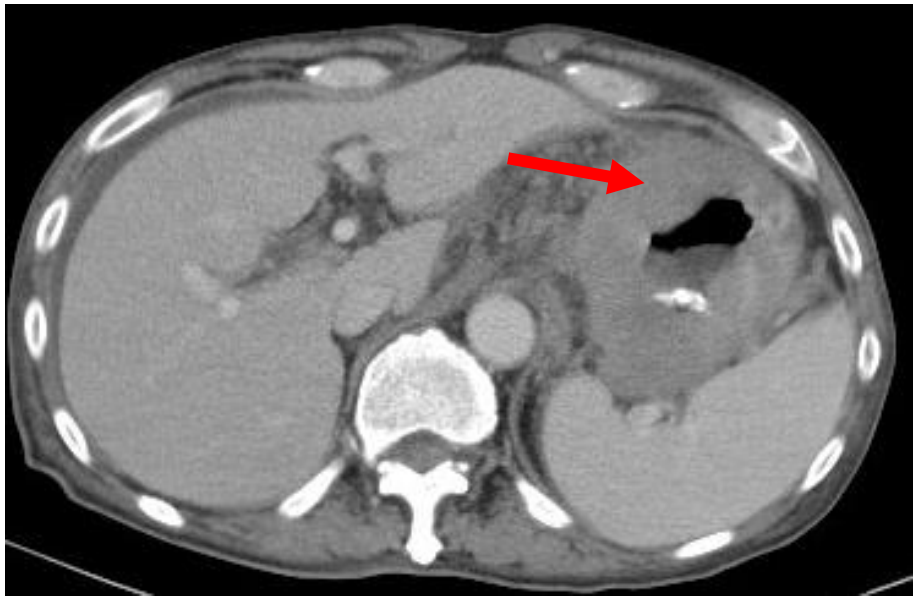
2014-2018

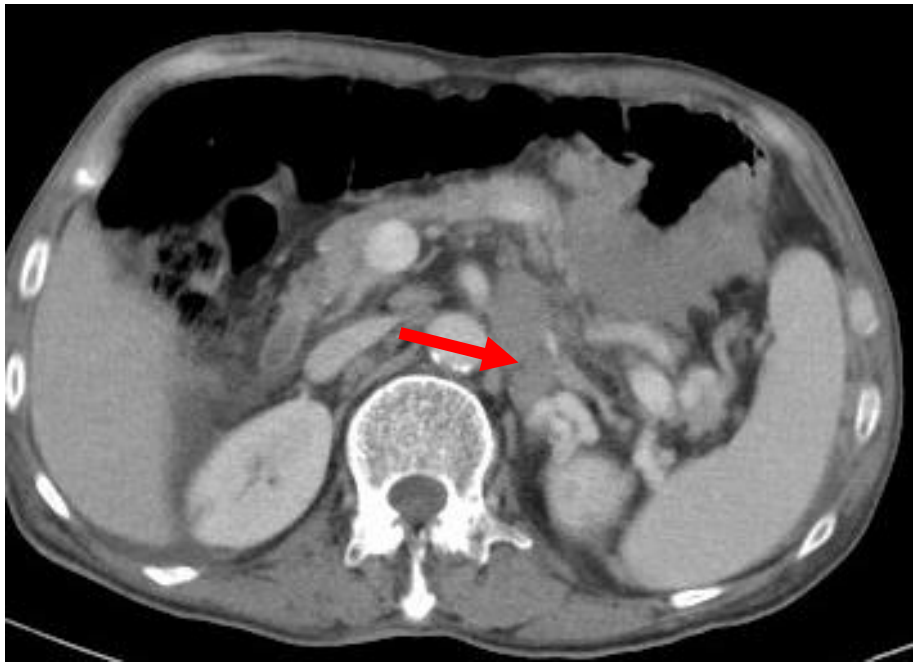
Trastuzumab (如Herceptin) 健保給付

- 3.轉移性胃癌(限IV 劑型)
  trastuzumab合併capecitabine (或5-fluorouracil)及cisplatin適用於未曾接受過化學治療之HER2過度表現(IHC3+或FISH+)轉移性胃腺癌(或胃食道接合處腺癌)的治療。(109/2/1)

- 經事前審查核准後使用，核准後每24週須檢附療效評估資料再次申請，若疾病有惡化情形即不應再行申請(105/11/1)。

202005





75 M, left MCA infarction, UGIB,

ECOG PS:4

PES Bx: adenocarcinoma

HER-2: 2+, do FISH

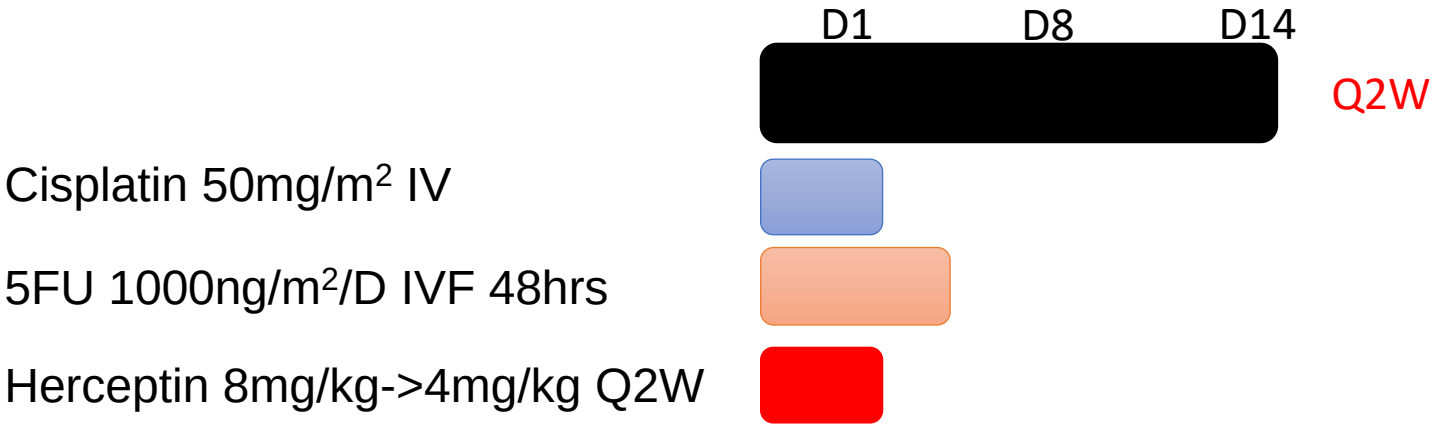
Stop bleeding, plt : 70k

2020/6/15 FOLFOX

FISH: +, apply Herceptin

2020/6/29 PF

2020/7/15 + Herceptin



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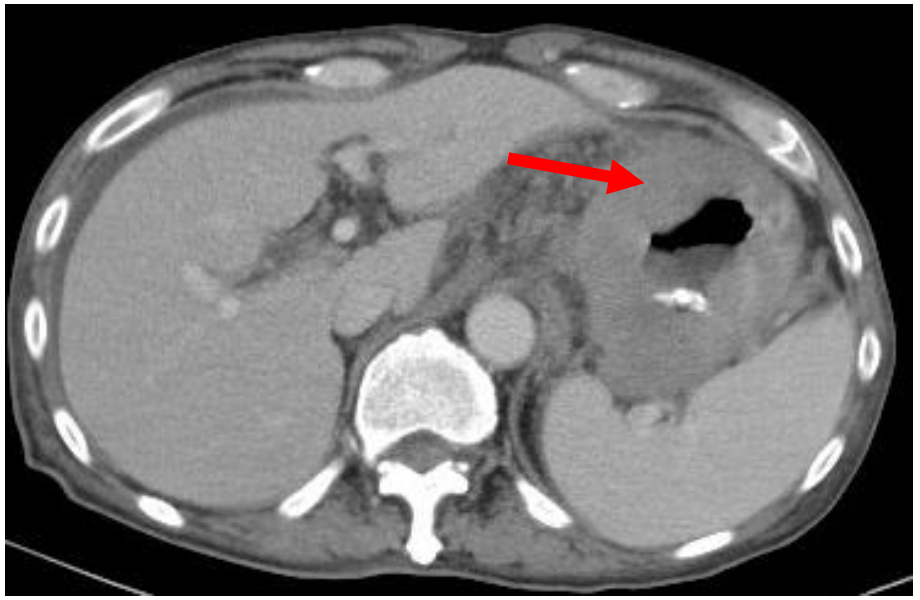
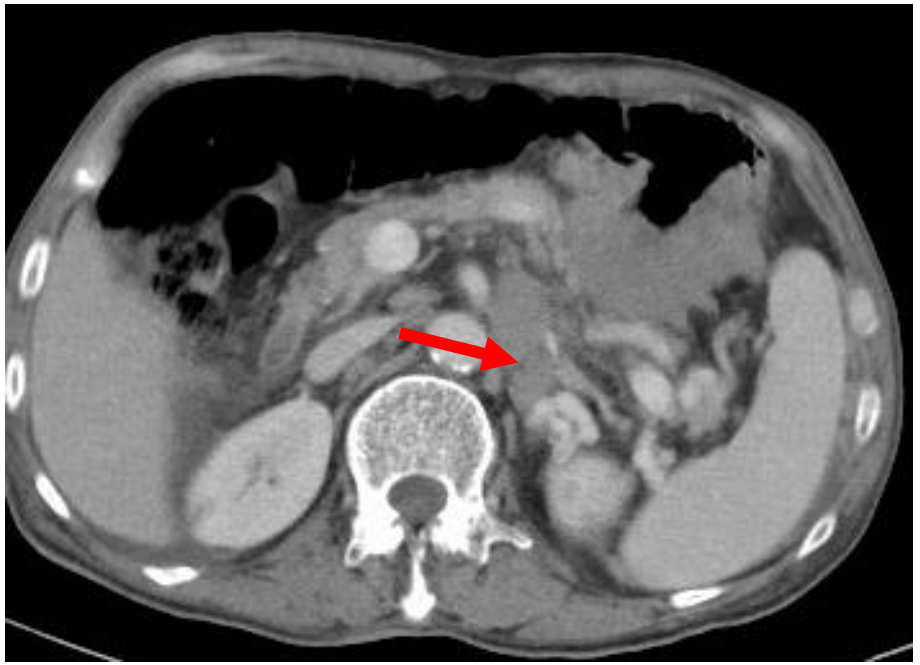
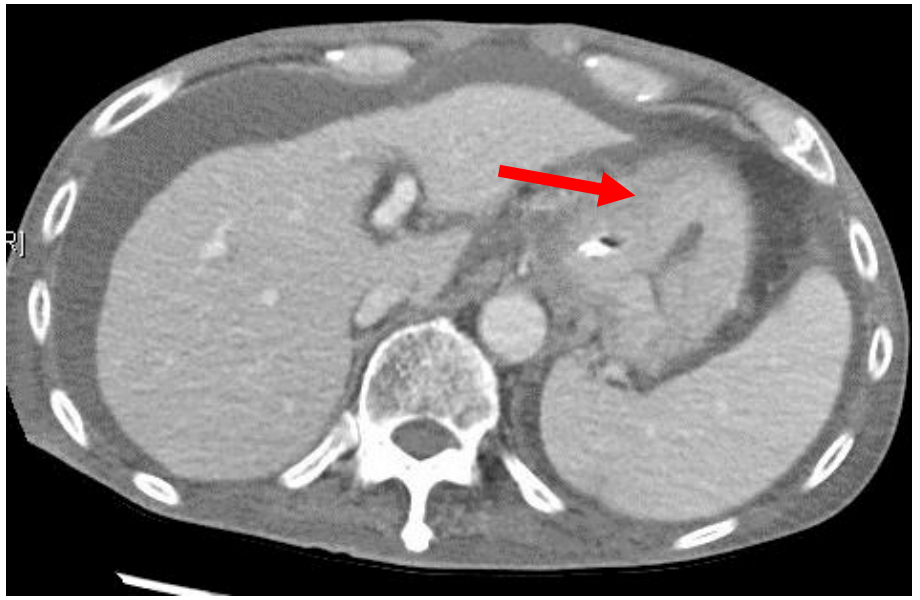
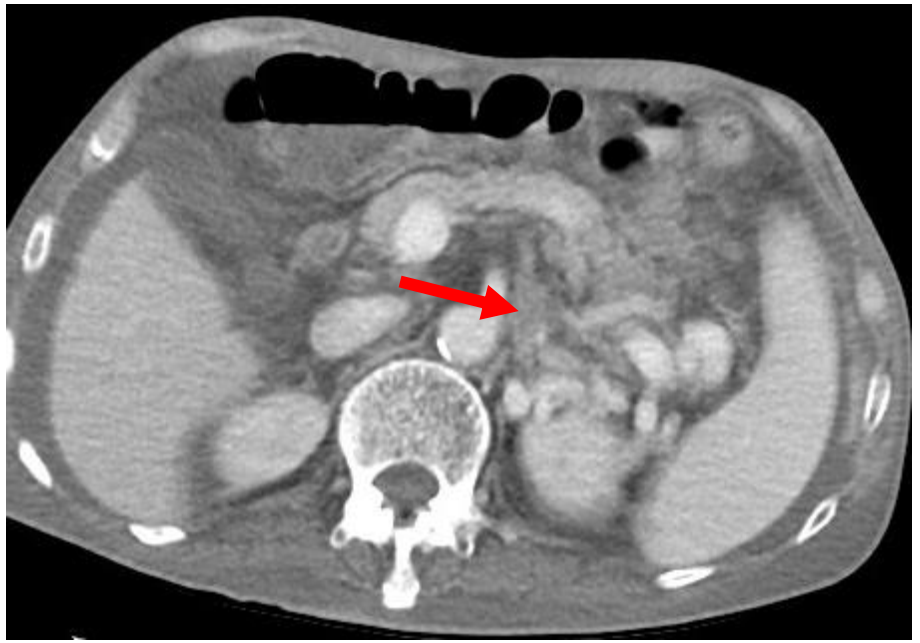




202009





2020/11
Expired

Summary

- ToGA trial: Herceptin improved the survival in first-line HER-2 positive advanced gastric adenocarcinoma patients (IHC3+ and IHC2+/FISH+)
- RWE demonstrated compatible efficacy with ToGA trial
- Oxaliplatin-based regimen is tolerable and comparable in response and survival when comparing to cisplatin-based regimen, however, this combination with Herceptin is not reimbursed by Taiwan NHI.