Case presentation
Metastatic oeso-gastric cancer

WHY we need an Asian guideline for oeso-gastric cancer?

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Department of Clinical Oncology
St. Marianna University School of Medicine
DISCLOSURE SLIDE

- Personal financial interests (Lecture fee): Eli Lilly Japan, Taiho Pharm, Chugai Pharm, Takeda Pharm, Merck Serono, Bristol-Myers Squibb, Ono Pharm, Bayer Yakuhin, Dainippon Sumitomo Pharm, Kyowa Hakko-Kirin, Sawai Pharm, Maruho Co., Ltd, Mochida Pharm, MSD K.K.

- Personal financial interests (Research finding): Taiho Pharm, MSD K.K., Ono Pharm, Sanofi, Chugai Pharm, AstraZeneca, Merck Serono, Takeda Pharm, Daiichi Sankyo, Eli Lilly Japan, Yakuruto Honsha, Eisai

- Institutional financial interests: Taiho Pharm, MSD K.K., Ono Pharm, Sanofi, Chugai Pharm, AstraZeneca, Daiichi Sankyo, Dainippon Sumitomo Pharm, Eisai, Amgen Astellas BioPharma, Eli Lilly Japan
## Patients Characteristics in F+CDDP arm for GC in 2000s

<table>
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<tr>
<th></th>
<th>WESTERN FLAGS</th>
<th>EU EORTC40902</th>
<th>Korea/China+α ML17032</th>
<th>Japan SPIRITS</th>
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</thead>
<tbody>
<tr>
<td><strong>No. of patients</strong></td>
<td>521</td>
<td>134</td>
<td>160</td>
<td>148</td>
</tr>
<tr>
<td><strong>Regimen</strong></td>
<td>SP</td>
<td>FP</td>
<td>XP</td>
<td>SP</td>
</tr>
<tr>
<td><strong>GEJ(%)</strong></td>
<td>16</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Histological type</strong></td>
<td>52/60/-</td>
<td>49/32/0</td>
<td>-</td>
<td>30/70/0</td>
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<tr>
<td>intestinal/diffuse/mix</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Target lesion</strong></td>
<td>4</td>
<td>37</td>
<td>-</td>
<td>41</td>
</tr>
<tr>
<td>- (%)</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Peritoneum</strong></td>
<td>-</td>
<td>11</td>
<td>19</td>
<td>34</td>
</tr>
<tr>
<td>+ (%)</td>
<td></td>
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## Efficacy in F+CDDP arm for GC in 2000s

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<td><strong>No. of patients</strong></td>
<td>521</td>
<td>134</td>
<td>160</td>
<td>148</td>
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<tr>
<td><strong>Regimen</strong></td>
<td>SP</td>
<td>FP</td>
<td>XP</td>
<td>SP</td>
</tr>
<tr>
<td><strong>RR</strong></td>
<td>29%</td>
<td>20%</td>
<td>46%</td>
<td>54%</td>
</tr>
<tr>
<td><strong>PFS</strong></td>
<td>4.8M</td>
<td>4.1M</td>
<td>5.6M</td>
<td>6.0M</td>
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<tr>
<td><strong>OS</strong></td>
<td>8.6M</td>
<td>7.2M</td>
<td>9.3M</td>
<td>13.0M</td>
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<tr>
<td><strong>2nd-line</strong></td>
<td>29%</td>
<td>-</td>
<td>-</td>
<td>74%</td>
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</table>

Sources:
- Ajani, JA, JCO 2010
- Vanhoefer U, JCO 2000
- Kang, YK, Ann of Oncol 2009
- Koizumi, W, Lan Oncol 2008
Patient

64-year-old Japanese man

Past History: nothing particular
Social History: Cigarette smoking: none, Alcohol: Occasionally
Family History: nothing particular

History of Present Illness:
Mar. 2015: Distal gastrectomy for gastric cancer located in the middle third
Path: sig>por ad-ca, pT1bN1M0 StageIB PM0 DM0
Mar. 2016: CT scan on postoperative F/U demonstrated the peritoneal nodules and ascites suggesting recurrence of gastric cancer.
Physical Examination

Height: 165cm, Weight: 52kg, Pulse: 65/min, BP: 104/67mmHg
SpO₂: 99% (room air), Temperature: 36.8 degree

Heart: no murmur, regular
Lung: no crackles
Abdomen: distended, no mass, tenderness(-), rebound tenderness(-)
sound: diminished

ECOG PS: 1

Anorexia: grade 1 (CTCAE v4.0)
Abdominal distention: grade 1
Nausea: grade 1
Vomitting: grade 0
Constipation: grade 1
Laboratory Tests

<table>
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<tr>
<th>Test</th>
<th>Value</th>
<th>Unit</th>
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<tr>
<td>WBC</td>
<td>7900</td>
<td>/μl</td>
</tr>
<tr>
<td>Neu</td>
<td>69</td>
<td>%</td>
</tr>
<tr>
<td>Hb</td>
<td>12.5</td>
<td>g/dl</td>
</tr>
<tr>
<td>Plt</td>
<td>36.1x10^4</td>
<td>/μl</td>
</tr>
<tr>
<td>TP</td>
<td>6.2</td>
<td>g/dl</td>
</tr>
<tr>
<td>Alb</td>
<td>3.2</td>
<td>g/dl</td>
</tr>
<tr>
<td>T-Bil</td>
<td>0.9</td>
<td>mg/dl</td>
</tr>
<tr>
<td>AST</td>
<td>23</td>
<td>IU/l</td>
</tr>
<tr>
<td>ALT</td>
<td>32</td>
<td>IU/l</td>
</tr>
<tr>
<td>LDH</td>
<td>129</td>
<td>IU/l</td>
</tr>
<tr>
<td>CRP</td>
<td>0.46</td>
<td>mg/dl</td>
</tr>
<tr>
<td>Na</td>
<td>137</td>
<td>mEq/l</td>
</tr>
<tr>
<td>K</td>
<td>4.5</td>
<td>mEq/l</td>
</tr>
<tr>
<td>Cl</td>
<td>98</td>
<td>mEq/l</td>
</tr>
<tr>
<td>UN</td>
<td>11.9</td>
<td>IU/l</td>
</tr>
<tr>
<td>Cr</td>
<td>0.71</td>
<td>mg/dl</td>
</tr>
<tr>
<td>CA19-9</td>
<td>59.7</td>
<td>U/ml</td>
</tr>
<tr>
<td>CEA</td>
<td>1.8</td>
<td>ng/ml</td>
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</table>
Summary

- 64-year-old Japanese male with recurrent gastric cancer in peritoneum
- No complication
- PS: 1
- Moderate amount of ascites
- Anorexia: G1, Nausea: G1, Vomitting: G0, Constipation: G1
- Low serum albumin
1\textsuperscript{st}-line Chemotherapy in Western countries

Shah MA, JCO 2015

US Gastric Cancer Consortium (P-II)

Cutsem EV, JCO 2006

V325

Ajani JA, JCO 2010

FLAGS

Cunningham D, NEJM 2008

REAL2

FP vs S-1+CDDP

ECF vs ECX vs EOF vs EOX

Winner!

Winner!

TOO TOXIC!!
1st-line Chemotherapy in ASIA

G-SOX

SPIRITS

GC0301/TOP002

START

P-III

Yamada Y, Ann Oncol 2015
Koizumi, W, J Cancer Res Clin Oncol 2014
Narahara H, Gastric Cancer 2011
Koizumi W, Lan Oncol 2008
Lu Z, Gastric Cancer 2018

S-1+CDDP vs S-1

S-1 vs S-1+CDDP (CS)

S-1+CPT-11 vs S-1+DTX

S-1 vs XP

S-1+OHP vs S-1+DTX

S-1+OHP vs X+PTX

Winner!

Winner!
Triplet Chemotherapy in ASIA

Yun J, EJC 2010
rP-II
XP vs ECX
Winner!

Yamada Y, ASCO 2018
JCOG 1013
CS vs DCS

Liu M, OncoTargets Therapy 2018
Retrospective
FOLFOX vs DOF

Retrospective
DCF vs mDCF
**CS vs DCS (JCOG1013)**

**PFS**

<table>
<thead>
<tr>
<th></th>
<th>CS</th>
<th>DCS</th>
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<tbody>
<tr>
<td>1-year PFS</td>
<td>25.9%</td>
<td>23.8%</td>
</tr>
<tr>
<td>(95% CI)</td>
<td>(21.5-30.4)</td>
<td>(19.6-28.2)</td>
</tr>
<tr>
<td>Median PFS</td>
<td>6.5 m</td>
<td>7.4 m</td>
</tr>
<tr>
<td>(95% CI)</td>
<td>(5.9-7.4)</td>
<td>(6.7-7.8)</td>
</tr>
<tr>
<td>HR (95% CI)</td>
<td>0.99 (0.86-1.15)</td>
<td>0.92 (0.86-1.15)</td>
</tr>
<tr>
<td>p value</td>
<td>0.92</td>
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**OS**

<table>
<thead>
<tr>
<th></th>
<th>CS</th>
<th>DCS</th>
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</thead>
<tbody>
<tr>
<td>1-year OS</td>
<td>61.5%</td>
<td>59.7%</td>
</tr>
<tr>
<td>(95% CI)</td>
<td>(56.3-66.2)</td>
<td>(54.5-64.5)</td>
</tr>
<tr>
<td>Median OS</td>
<td>15.3 m</td>
<td>14.2 m</td>
</tr>
<tr>
<td>(95% CI)</td>
<td>(14.2-16.2)</td>
<td>(12.9-15.9)</td>
</tr>
<tr>
<td>HR (95% CI)</td>
<td>0.99 (0.85-1.16)</td>
<td>0.99 (0.85-1.16)</td>
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<tr>
<td>p value</td>
<td>0.47</td>
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</table>
Gastric cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up†
E. C. Smyth1, M. Verheij2, W. Allum3, D. Cunningham4, A. Cervantes5 & D. Arnold6 on behalf of the ESMO Guidelines Committee†

First-line treatment
- Doublet or triplet platinum/fluoropyrimidine combinations are recommended for fit patients with advanced gastric cancer [I, A]
- Capecitabine is associated with improved OS compared with infused 5-FU within doublet and triplet regimens [I, A]
- DCF in a 3-weekly regimen was associated with improved OS, but also added significant toxic effects including increased rates of febrile neutropenia [I, C]

Recommendation 4: First-line treatment

4a-1. Doublet platinum/fluoropyrimidine combinations are recommended for fit patients with advanced gastric cancer [A=100% and I, A].

4a-2. A triplet regimen comprising platinum/fluoropyrimidine/taxane is an option for fit patients with advanced gastric cancer [A=83%, B=17% and I, A].

4c. Capecitabine is associated with improved OS compared with infused 5-FU within doublet and triplet regimens [I, A], was revised to read Capecitabine or S-1 can be used as an alternative to infusional 5-FU in doublet regimens [A=100% and I, A].
Clinical course

History of Present Illness:
Mar. 2015: Distal gastrectomy for gastric cancer located in the middle third
Path: sig>por ad-ca, pT1bN1M0 StageIb PM0 DM0
Mar. 2016: CT scan on postoperative F/U demonstrated the peritoneal nodules and severe ascites suggesting recurrence of gastric cancer.
Apr. 2016: S-1+Oxaliplatin (SOX) started (HER2 negative)

<table>
<thead>
<tr>
<th>Drugs</th>
<th>CSCO China</th>
<th>JSMO Japan</th>
<th>KSMO Korea</th>
<th>MOS Malaysia</th>
<th>SSO Singapore</th>
<th>TOS Taiwan</th>
<th>ESMO MCBS V1.1[128, 129]</th>
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<tbody>
<tr>
<td></td>
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<td>Approved</td>
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<tr>
<td>S-1</td>
<td>Green</td>
<td>Red/Gray</td>
<td>Green</td>
<td>Green</td>
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<td>Oxaliplatin</td>
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CYP2A6 polymorphisms and S-1 metabolism

<table>
<thead>
<tr>
<th>Polymorphism</th>
<th>Asians (n=13)</th>
<th>Caucasian (n=19)</th>
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<tr>
<td>CYP2A6*4</td>
<td>5%</td>
<td>0%</td>
</tr>
<tr>
<td>CYP2A6*7</td>
<td>8%</td>
<td>0%</td>
</tr>
<tr>
<td>CYP2A6*9</td>
<td>35%</td>
<td>8%</td>
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</tbody>
</table>

B. Chuah  Cancer Science  102 (2) 478—483, 2011
P-I study of S-1/CDDP in Caucasian

**LEVEL 1**
- S-1 50mg/m²
- CDDP 75mg/m²
- DLT = 0/3
- DLT = 0/6  RD

**LEVEL 2**
- S-1 60mg/m²
- CDDP 75mg/m²
- DLT = 2/3

**LEVEL 1A**
- S-1 60mg/m²
- CDDP 60mg/m²
- DLT = 1/3 4/6

Japanese: S-1 80mg/m²
CDDP 60mg/m²

CT scan after 2 courses of SOX
Progression after 9 courses of SOX

Abdominal X ray

Abdominal CT
### 2\textsuperscript{ND}-line Chemotherapy vs BSC

<table>
<thead>
<tr>
<th>TRIAL</th>
<th>PHASE</th>
<th>N</th>
<th>1st-line PE</th>
<th>ARMS</th>
<th>RR(%)</th>
<th>PFS(M)</th>
<th>OS(M)</th>
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<tbody>
<tr>
<td>AIO</td>
<td>III</td>
<td>40</td>
<td>CDDP</td>
<td>OS</td>
<td>-</td>
<td>2.6</td>
<td>2.4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>containing</td>
<td>BSC</td>
<td>-</td>
<td>2.5</td>
<td>4</td>
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<td></td>
<td></td>
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<td>CPT-11</td>
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<tr>
<td>COUGAR-02</td>
<td>III</td>
<td>168</td>
<td>5-FU and platinum</td>
<td>BSC</td>
<td>-</td>
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<td>REGARD</td>
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<td>355</td>
<td>5-FU and/or platinum</td>
<td>BSC</td>
<td>3</td>
<td>1.3</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Ramucirumab</td>
<td>3</td>
<td>2.1</td>
<td>5.3</td>
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<td>KOREA</td>
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<td>202</td>
<td>5-FU and/or platinum</td>
<td>BSC</td>
<td>-</td>
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<td>3.8</td>
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<td>CPT-11 or DTX</td>
<td>9.5</td>
<td>-</td>
<td>5.3</td>
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- **HR 0.48**
- **HR 0.67**
- **HR 0.483**
- **HR 0.776**
- **HR 0.657**

**References:**
- Thuss-Patience PC EJC 2011
- Ford HER Lancet Oncol 2014
- Fuchs CS Lancet 2014
- Kang JH JCO 2012
<table>
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<tr>
<th>Trial</th>
<th>Phase</th>
<th>N</th>
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<th>PE</th>
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<th>PFS(M)</th>
<th>OS(M)</th>
<th>HR in OS</th>
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<tr>
<td>WJOG4007</td>
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<td>219</td>
<td>5-FU + platinum</td>
<td>OS</td>
<td>wPTX</td>
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<td>130</td>
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<td>CPT-11</td>
<td>16.4</td>
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<td>4.6</td>
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<td>300</td>
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<td>3.4</td>
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<td>S-1 + CPT-11</td>
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<td>nab-PTX q1w</td>
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<td>5.3</td>
<td>11.1</td>
<td>0.97</td>
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<td></td>
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<td>25</td>
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<td>10.3</td>
<td>1.06</td>
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<td>RAINBOW</td>
<td>III</td>
<td>665</td>
<td>5-FU + platinum</td>
<td>OS</td>
<td>wPTX</td>
<td>16</td>
<td>2.9</td>
<td>7.4</td>
<td></td>
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<tr>
<td></td>
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<td>wPTX + Ramucirumab</td>
<td>27</td>
<td>4.4</td>
<td>9.6</td>
<td>0.807</td>
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</table>

References:
- Hironaka S (JCO 2013)
- Higuchi K (EJC 2014)
- Nishikawa K (EJC 2015)
- Shitara K (Lancet Gastro Hepato 2017)
- Wilke H (Lancet Oncol 2014)
Gastric cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up†

E. C. Smyth1, M. Verheij2, W. Allum3, D. Cunningham4, A. Cervantes5 & D. Arnold6 on behalf of the ESMO Guidelines Committee*

Second- and further-line treatment

- Second-line chemotherapy with a taxane (docetaxel, paclitaxel), or irinotecan, or ramucirumab as a single agent or in combination with paclitaxel is recommended for patients who are of PS 0–1 [I, A]
- Similar efficacy has been demonstrated for weekly paclitaxel and irinotecan [I, A]

Recommendation 6: Second- and further-line treatment

6a. Second-line chemotherapy with a taxane (docetaxel, paclitaxel), or irinotecan, or ramucirumab as a single agent or in combination with paclitaxel is recommended for patients who are of PS 0–1 [A=100% and I, A].
Clinical course

Jan. 2017: SOX discontinued due to PD after 9 courses

Best response: SD

Aug. 2017: PTX+RAM discontinued due to PD after 9 courses
3rd-line≤ Chemotherapy vs BSC

Nivolumab

Apatinib

Kang YK, Lancet 2017

Li J, JCO 2016

Shitara K, Lancet Oncol 2018
Gastric cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up†

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Second- and further-line treatment

- Second-line chemotherapy with a taxane (docetaxel, paclitaxel), or irinotecan, or ramucirumab as a single agent or in combination with paclitaxel is recommended for patients who are of PS 0–1 [I, A]
- Similar efficacy has been demonstrated for weekly paclitaxel and irinotecan [I, A]

Recommendation 6: Second- and further-line treatment

6c. Nivolumab, pembrolizumab or trifluridine/tipiracil (TAS-102) should be considered as third- or further-line treatment, if approved. Irinotecan or a taxane (if not used in the earlier lines) are also options for third- or further-line treatment [A=100% and V, C]. Apatinib may also be considered but only in China [A=100% and I, A].
Clinical course

Jan. 2017: SOX discontinued due to PD after 9 courses

Aug. 2017: PTX+RAM discontinued due to PD after 9 courses


May. 2018 Passed away after 1 dose of CPT-11 (OS: 2.2y)
**UGT1A1 polymorphisms and CPT-11 metabolism**

**UGT1A1*28**
- **Race**
  - Japanese: 0.130, 301 (Saeki et al. 2006)
  - Korean: 0.127, 324 (Ki et al. 2003)
  - Caucasian: 0.388, 147 (Kaniwa et al. 2005)
  - African American: 0.446, 149 (Kaniwa et al. 2005)

**UGT1A1*6**
- **Race**
  - Japanese: 0.177, 116 (Kaniwa et al. 2005)
  - Korean: 0.157, 150 (Kaniwa et al. 2005)
  - Caucasian: 0.337, 132 (Innocenti et al. 2005)
  - African American: 0.426, 101 (Bottcher et al. 1998)

**Race**
- Japanese
- Korean
- Caucasian
- African American

**Publication**
- Saeki et al. 2006
- Kaniwa et al. 2005
- Ki et al. 2003
- Han et al. 2006
- Lampe et al. 1999
- Innocenti et al. 2005
- Bottcher et al. 1998
- Guillomotto et al. 2000
- Kanai et al. 2005
- Kaniwa et al. 2005
- Saeki et al. 2006
- Akaba et al. 1998
- Han et al. 2006
- Ki et al. 2003
- Kaniwa et al. 2005
- Innocenti et al. 2005
- Thomas et al. 2006
- Kaniwa et al. 2005

**Notes**
- ND: Not determined
WHY we need an Asian guideline for oeso-gastric cancer?

➢ Clinicopathological background
➢ Strategy of development
➢ Genetic background

- Partially different between European and Asian
- Should be carefully observed concerning toxicity

Share the basic perspectives among EU and Asian countries through Pan-Asian adapted ESMO guideline
Thank you for your kind attention!