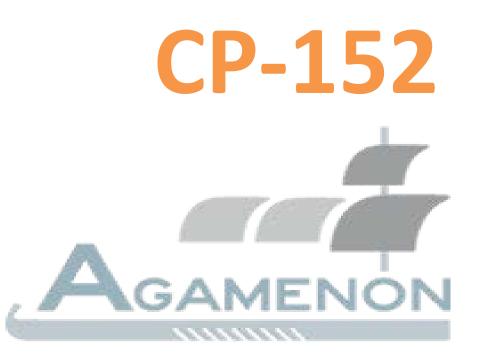


Applying the Results from the TOGA Trial into Clinical Practice: Data from the AGAMENON Multicentre Study



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Objective

To evaluate the efficacy of trastuzumab in combination with a wider variety of first-line chemotherapy regimens in a multicentre cohort of patients with HER-2 positive advanced gastric or gastro-oesophageal junction adenocarcinoma in clinical practice.

Materials and methods

AGAMENON is a multicentre observational study to assess prognostic factors and patterns of care in advanced gastric or gastroesphageal junction cancer treated with polichemotherapy between 2008 and 2016. Clinical data were obtained by medical record review after approval by the ethics committee and introduced into the website of the study. The main clinical variables,: progression free survival (PFS) and overall survival (OS), were analysed using the Kaplan-Meier method. HER2 positivity was defined by immunohistochemistry (IHC) 3+ or IHC2 +/fluorescence in situ hybridization (FISH)+.

Results and Discussion

- Clinical Clinical baseline characteristics are shown in Table 1 and compared with TOGA trial¹
- Patients were treated with trastuzumab for a median of 7 months (10 cycles). Median lines of treatment received were 1 (range 1–4).
- The majority of patients maintain trastuzumab in consecutive lines.

Figure 1. Profile of treatments received by the patients.

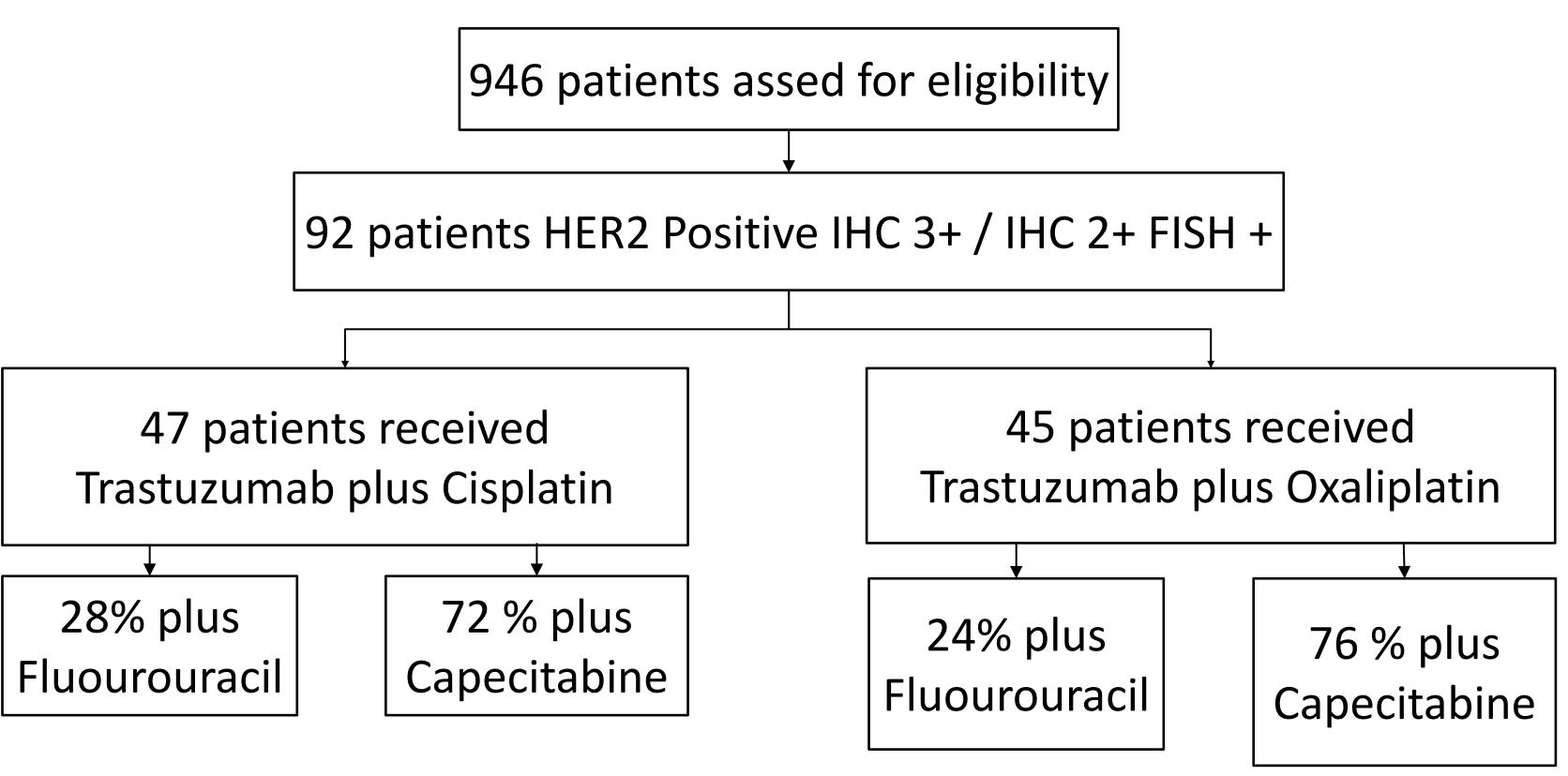


Table 2 summarizes study results

| | Agamenon Study n=92 | TOGA Trial n=292 |
|--------------------|---------------------|------------------|
| Follow up (months) | 27,2 (16-38) | 18,6 (11-25) |
| RR | 61% | 47% |
| PFS | 8.8 (8-11) | 6.7 (6-8) |
| Survival | 19.3 (12-24) | 13.8 (12-16) |

PFS: progression free survival.

RR: response rate.

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| 0.8 | 8- | | \ \ | | | | Pr | rogres | ssion | Free | Survi | ival | |
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| Survival Probability | 6 | | | | | | | | | | | | |
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| 0 | 2 | | | | | | | 1 | 1 | | | | |
| 0. | 1 | 8.8 | | 19.3 | 3 | | | | | | | | |
| 0.0 | $_{D} +$ | | T | | 1 | | T | | 1 | | T | | |
| | 0 | | 10 | | 20 | T: | 30 | 4.1 \ | 40 | | 50 | | 60 |
| Number at risk Time (months) | | | | | | | | | | | | | |
| OS PFS | 90 89 | 79 67 | 55 36 | 40 22 | 33 12 | 24 9 | 16 8 | 13 8 | 6 4 | 6 2 | 3 1 | 1 0 | 0 0 |

Figure 2 shows survival curves

| CLINICAL BASELNE CHARACTERISTICS | Agamenon Study n=92 | TOGA Trial n=292 | | | | | |
|---------------------------------------|------------------------|-----------------------|--|--|--|--|--|
| Age (years) | 64.5 (10.8) | 59.4 (10.8) | | | | | |
| Men | 77% | 77% | | | | | |
| ECOG 0-1 | 91% | 90% | | | | | |
| Comorbidities < 2 | 87% | - | | | | | |
| Primary tumour site | | | | | | | |
| Gastroesophageal junction Stomach | 24% 76% | 20% 80% | | | | | |
| Lauren type | | | | | | | |
| Intestinal Diffuse Mixed No available | 77% 13% 4% 5% | 77% 9% 14% - | | | | | |
| Her2 Status | | | | | | | |
| ICH 3+ ICH 2+ / FISH + | 64% 36% | 65% 35% | | | | | |
| Metastasic sites per patient | | | | | | | |
| 1-2 >2 | 60% 40% | 52% 48% | | | | | |

Table 1. Clinical baseline characteristics of AGAMENON study patients compared with TOGA trial patients¹.

Conclusions

These outcomes are consistent with the efficacy data from the ToGA trial, showing a benefit from the association of trastuzumab with any chemotherapy in patients with advanced gastric or gastro-oesophageal junction cancer that overexpress HER2.

Acknowledgments and References