

A Randomized Phase III Study of Cisplatin with or without Raltitrexed in Patients with Malignant Pleural Mesothelioma (MPM): an Intergroup Study of the EORTC Lung Cancer Group and the NCIC

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Background

- **Relatively rare disease (2500 new patients a year in Europe and expected to double by 2018)**
- **MPM patients have a poor prognosis: Maintaining QOL is critical**
- **Yet little is known about QOL of patients with MPM: Dyspnoea is the major problem**
- **The disease is difficult to treat. Until recently, treatment options were limited, with generally no accepted standards. Treatment intent is palliative and recommended for only symptom control**
- **Cisplatin seems to be the most active (regarding response rates) chemotherapy**
- **Raltitrexed (Tomudex) looked promising agent to increase OS**

Study design

Stratification (n=250)

- WHO-PS
0 vs 1 – 2
- WBC count
<8.3x10⁹/l vs
≥8.3x10⁹/l

⑩ R

⑩ A

⑩ N

⑩ D

⑩ O

⑩ M

⑩ I

⑩ Z

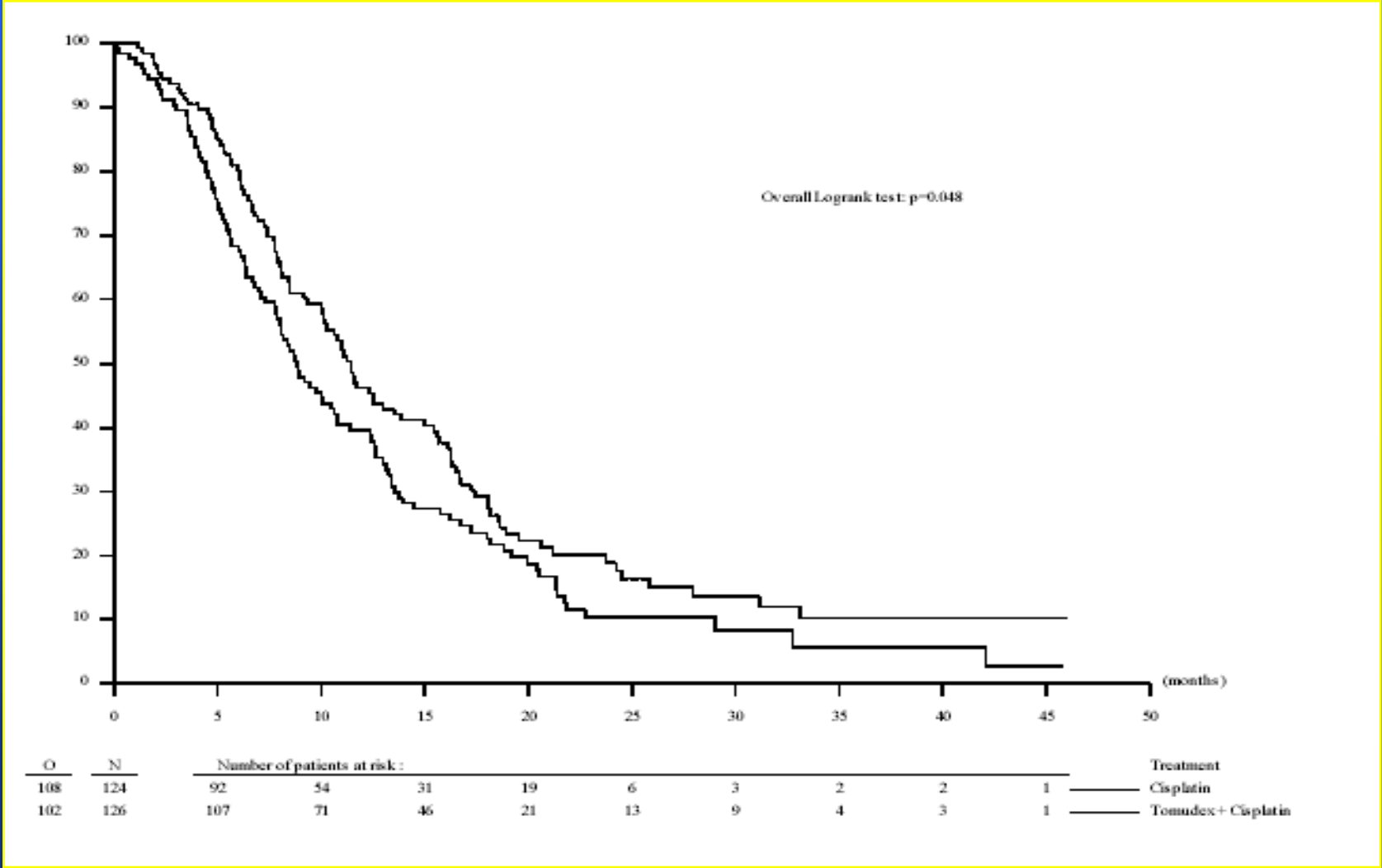
⑩ E

Arm A: cisplatin 80 mg/m² day 1
iv (n=125)

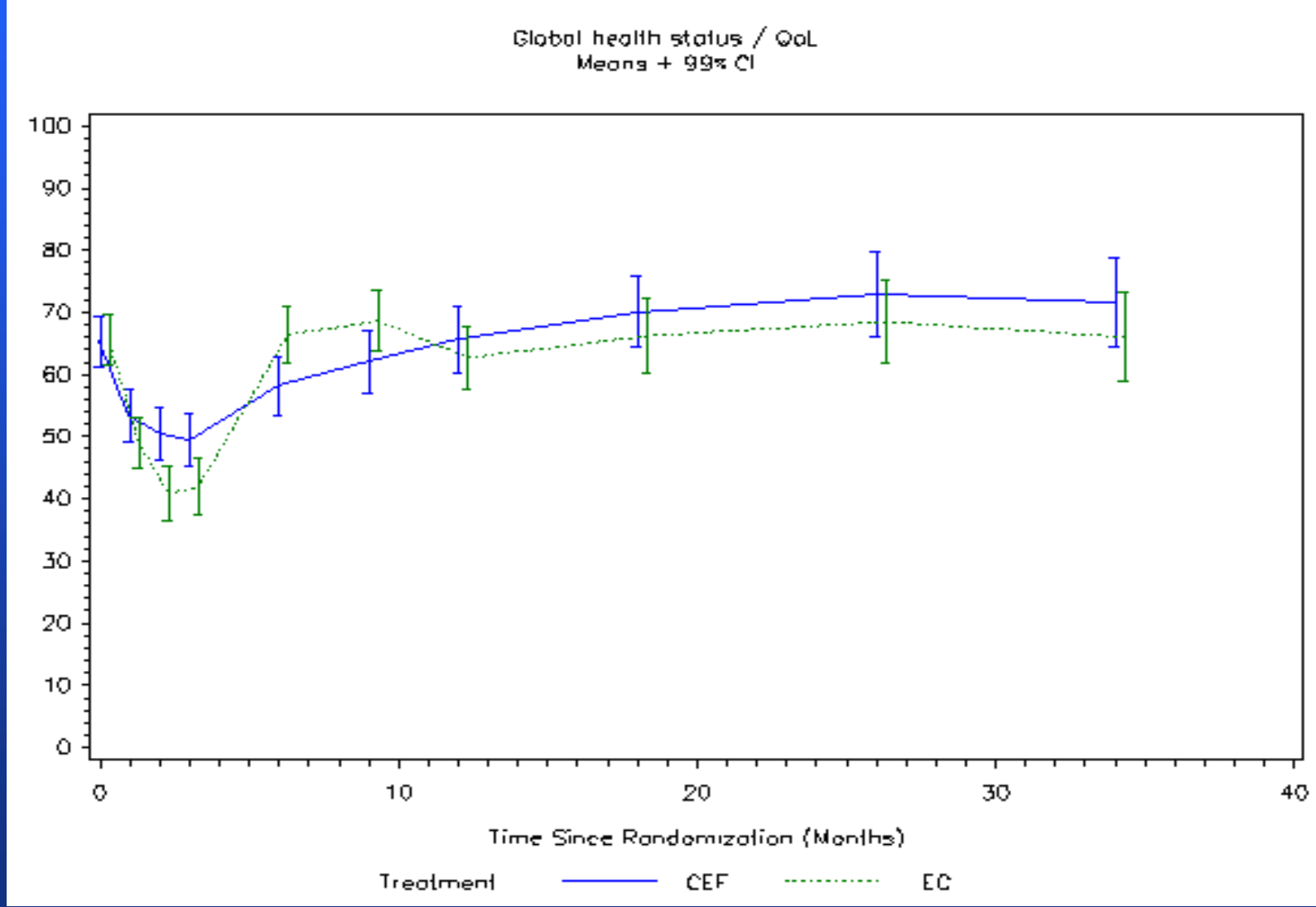
Arm B: Tomudex 3.0 mg/m² day 1
iv followed by cisplatin 80 mg/m²
day 1 iv (n=125)

⑩ Both q3w till PD, toxicity, refusal

Survival

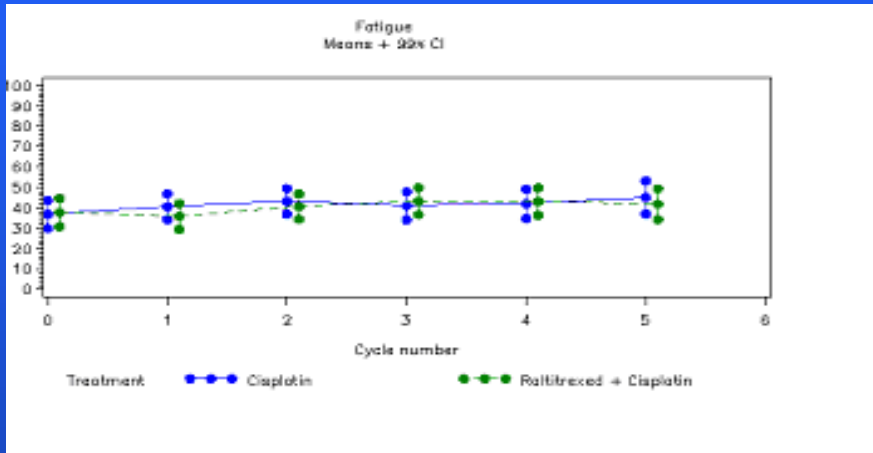


Global QoL

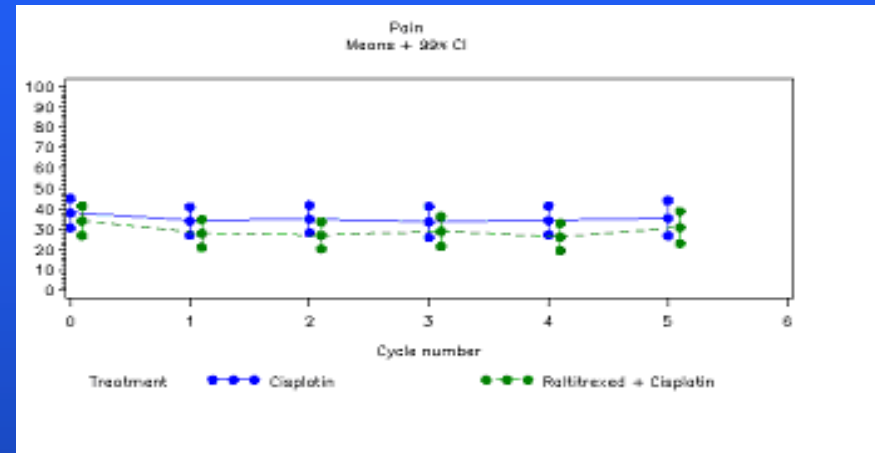


Selected other scales

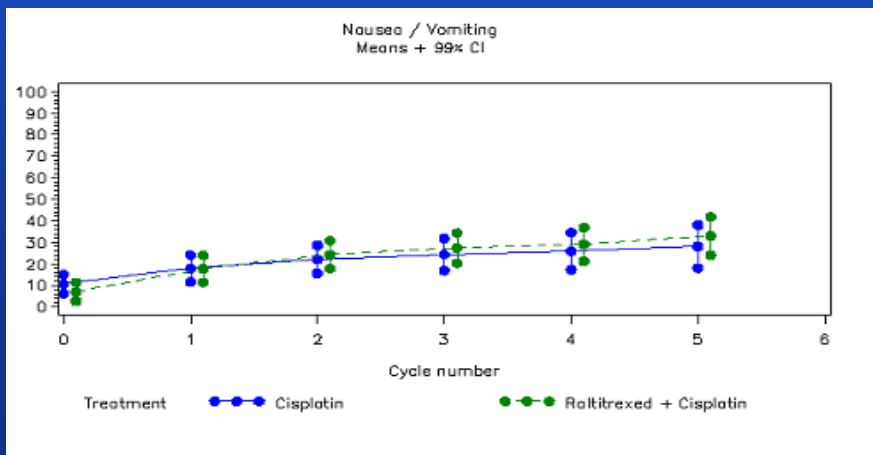
⑩ Fatigue



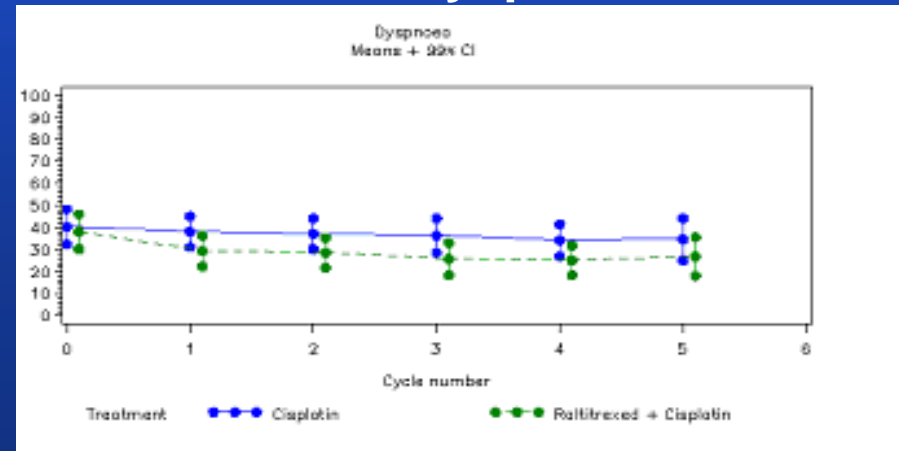
⑩ Pain



⑩ Nausea/Vomiting



⑩ Dyspnoea



- The addition of tomudex to cisplatin significantly improve survival in MPM patients
- There was no significant difference in QOL between either arm thereby given greater support for the use of raltitrexed with cisplatin. **However, Dyspnoea was lower in the tomudex arm, so some clear benefits are seen**
- This is key information to pass the clinicians and most importantly to the patients

- To continue to provide high quality studies that can **have an impact on patient care: Clinically relevant and important**
- To **maximize compliance** in international QOL trials to avoid excessive missing data
- QOL is already used in marketing (Letrozole, Epo) but be **careful and accurate**
- Educate groups such as EMEA about the value and methodological issues of QOL in clinical trials – Recent success from EORTC here consulting and helping to provide new EMEA guidelines