

HRQOL: The State of the Art in Oncology

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**Joint EORTC Brain Tumour
Group/Radiotherapy Group and
NCIC CTG phase III randomised
controlled trial evaluating
HRQOL in glioblastoma patients**

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Glioblastoma multiforme

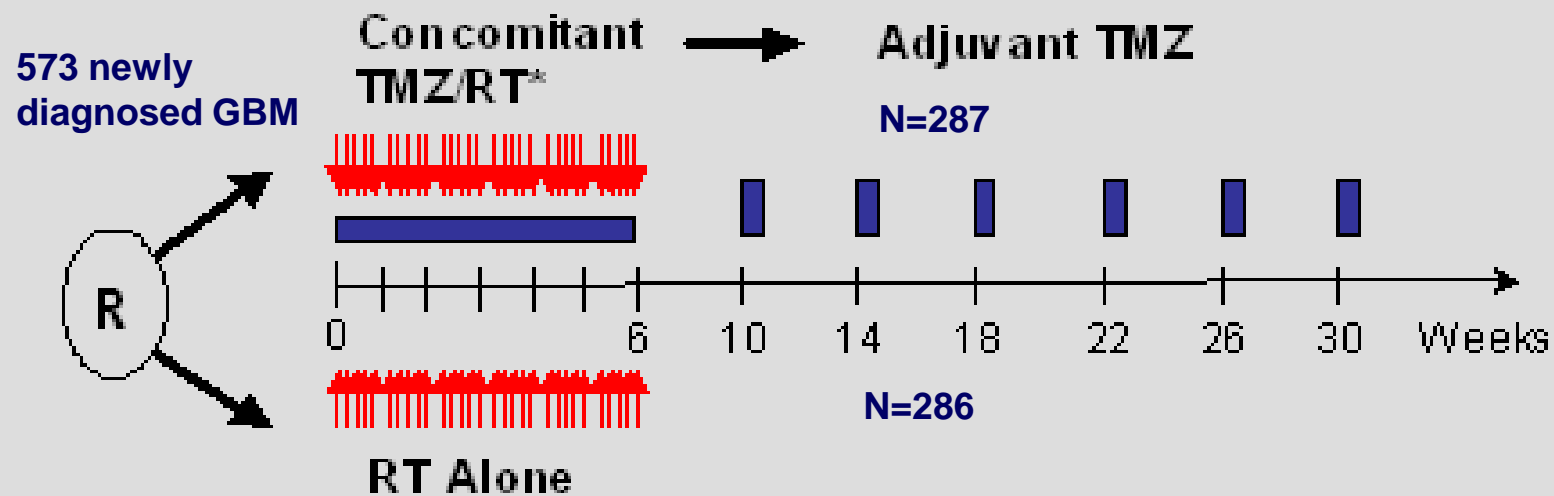
- **Most common primary brain tumour**
- **Treatment:**
 - **Adjuvant chemotherapy following RT, has been an issue of debate for years**
 - ◆ **In European countries/Canada, the limited survival benefit of adjuvant chemotherapy was not believed to outweigh treatment-related side effects**
 - **surgery: biopsy and/or resection**
 - **focal radiotherapy: 60 Gy in 30 fractions**
- **Prognosis:**
 - **patients die from recurrent disease in the brain**
 - **median survival: 9 - 12 months**



Rationale for phase III trial with adjuvant temozolomide

- TMZ has single agent activity
- Oral tablet
- TMZ is well tolerated with no negative impact on QoL (Osoba 2000)
- Promising clinical efficacy with TMZ/RT in a phase II trial (Stupp 2002)
- Little is known about QOL of these patients



Treatment Schema

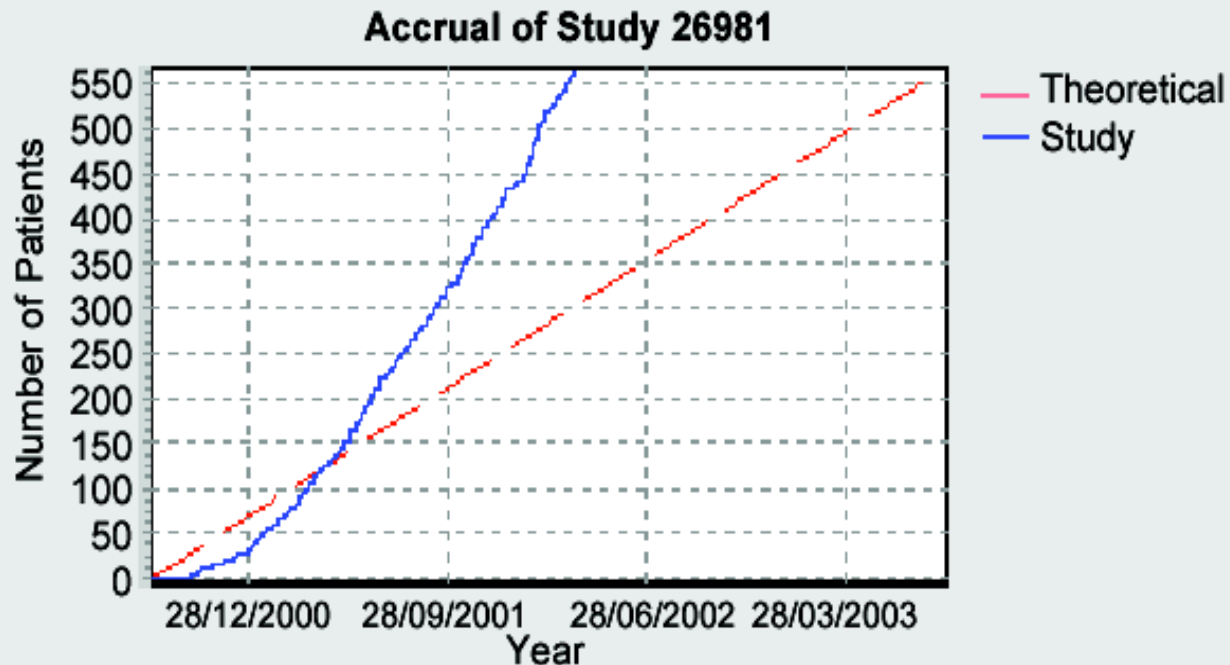


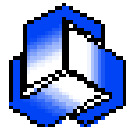
-  **Temozolomide** 75 mg/m² po qd for 6 weeks, then 150-200 mg/m² po qd d1-5 every 28 days for 6 cycles
-  **Focal RT** daily — 30 x 200 cGy
Total dose 60 Gy

*PCP prophylaxis was required for patients receiving TMZ during the concomitant phase.

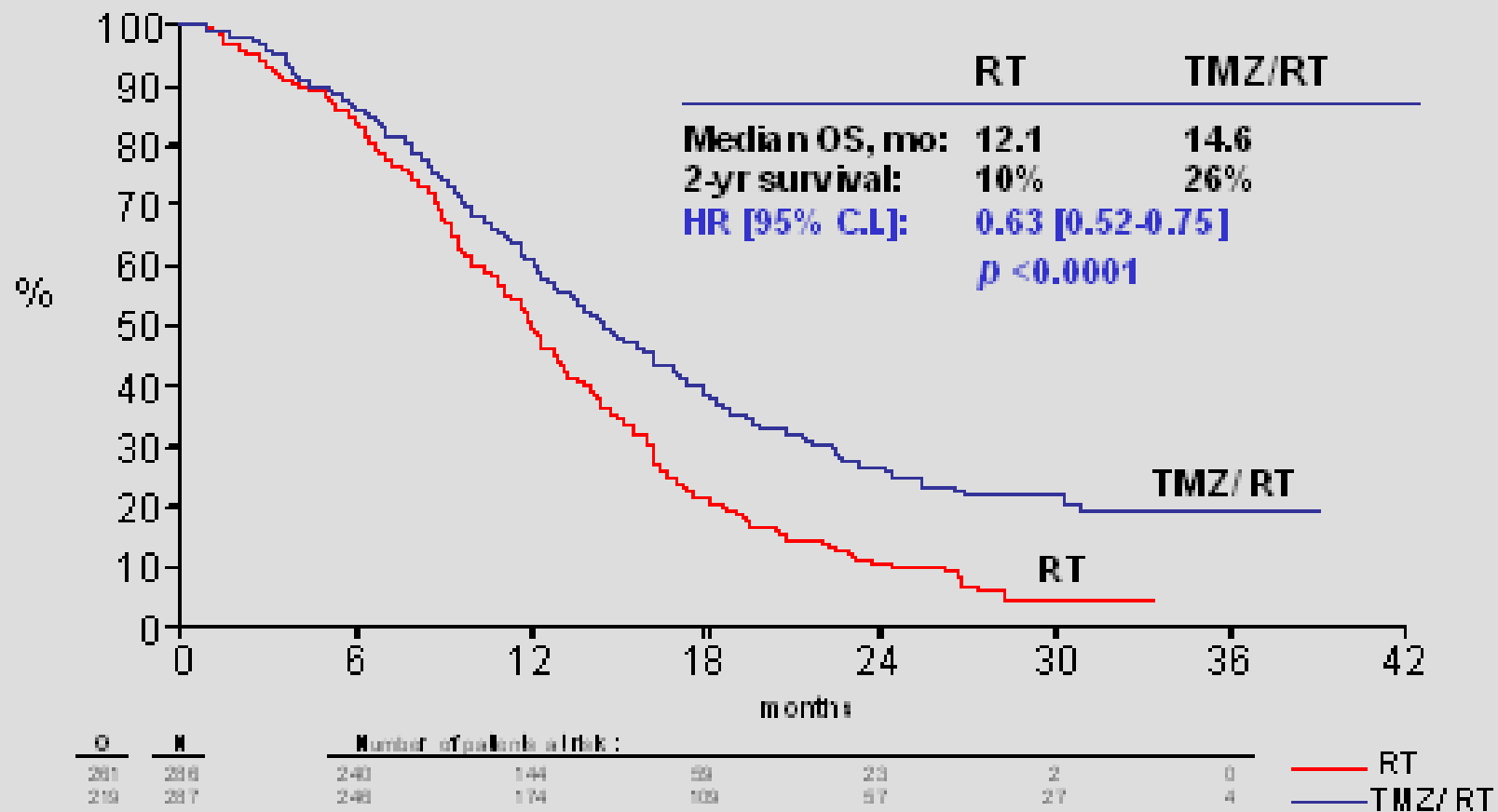
Radiotherapy / Temozolomide adjuvant study in Glioblastoma

- 85 institutions, 14 countries, 573 patients

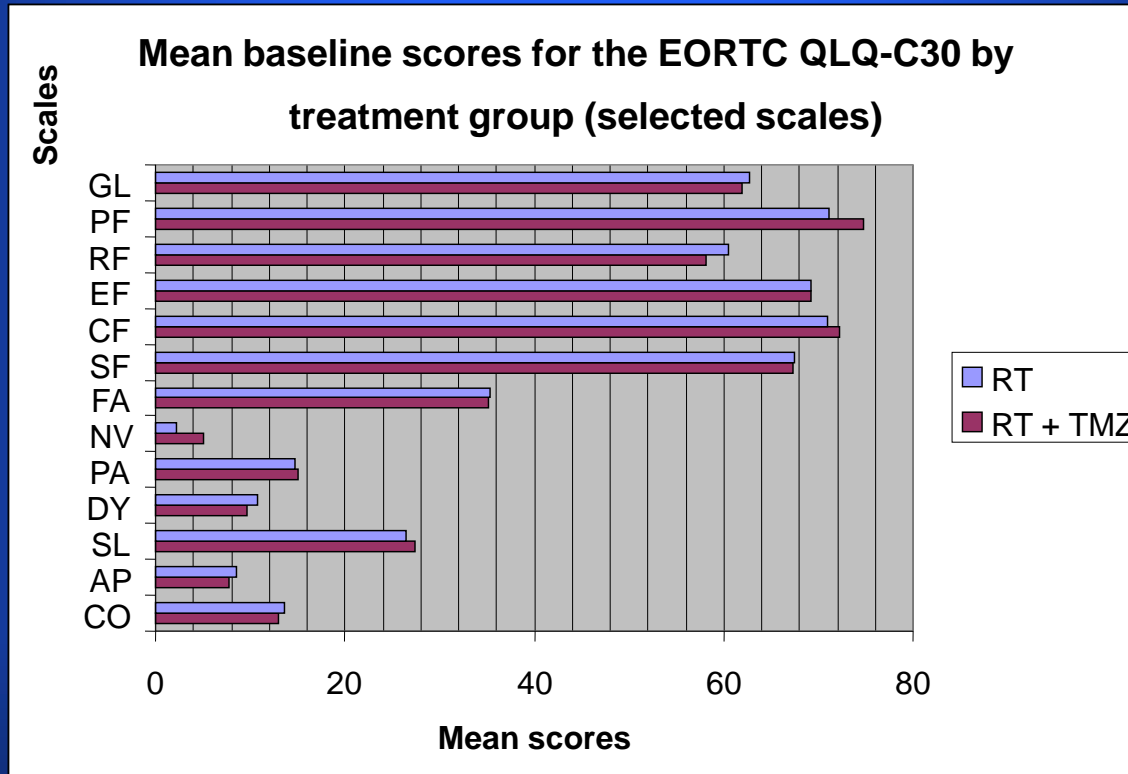




Overall Survival

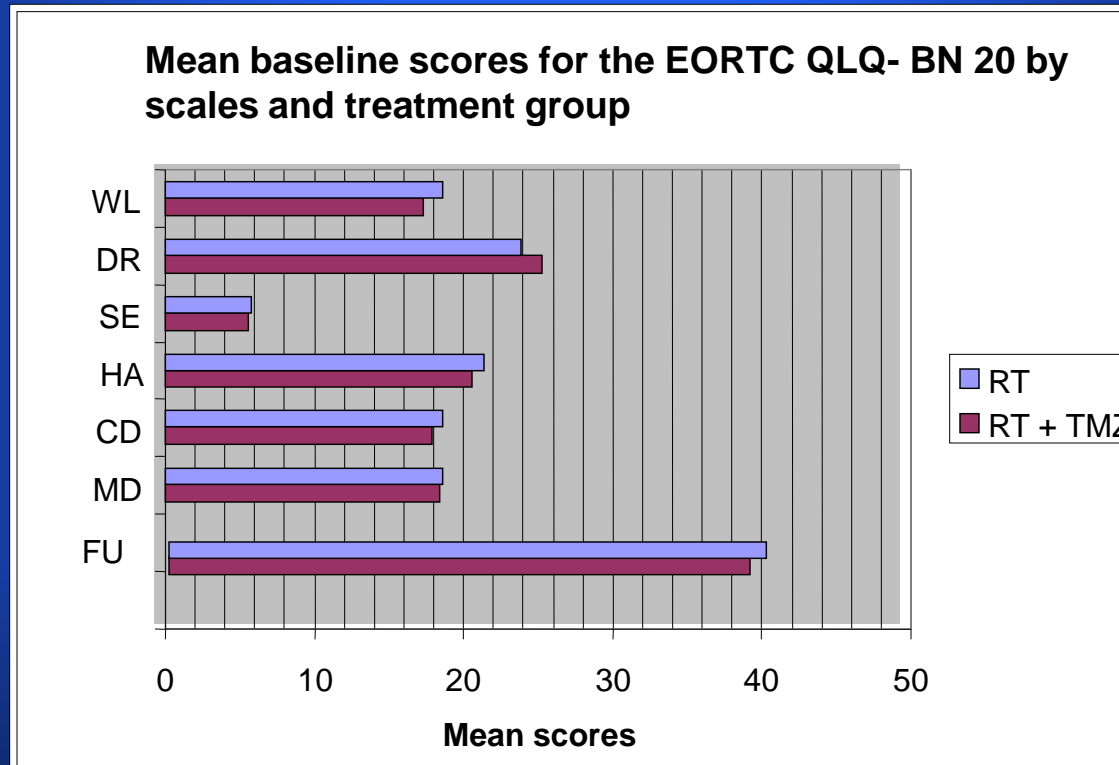


QOL results - Baseline



- functioning scale global QoL (GL) and role functioning (RF): low scores
- symptom scales fatigue (FA) and insomnia (SL): high scores
- no difference between treatment arms

QOL results - Baseline



- symptom scales future uncertainty (FU) and drowsiness (DR) high
- symptom scale seizures (SE) low
- no difference between treatment arms

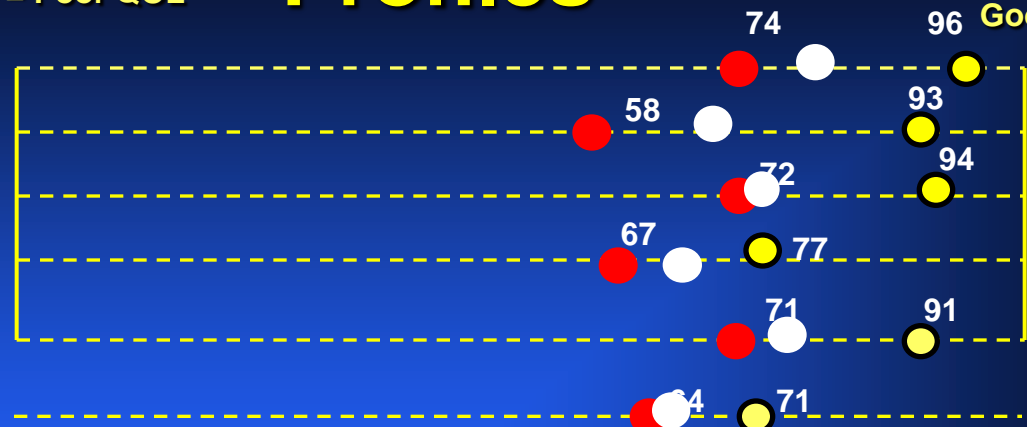
Profiles

0 = Poor QOL

100 = Good QOL

Functional scales

Physical functioning
 Role functioning
 Cognitive functioning
 Emotional functioning
 Social functioning
 Global health status

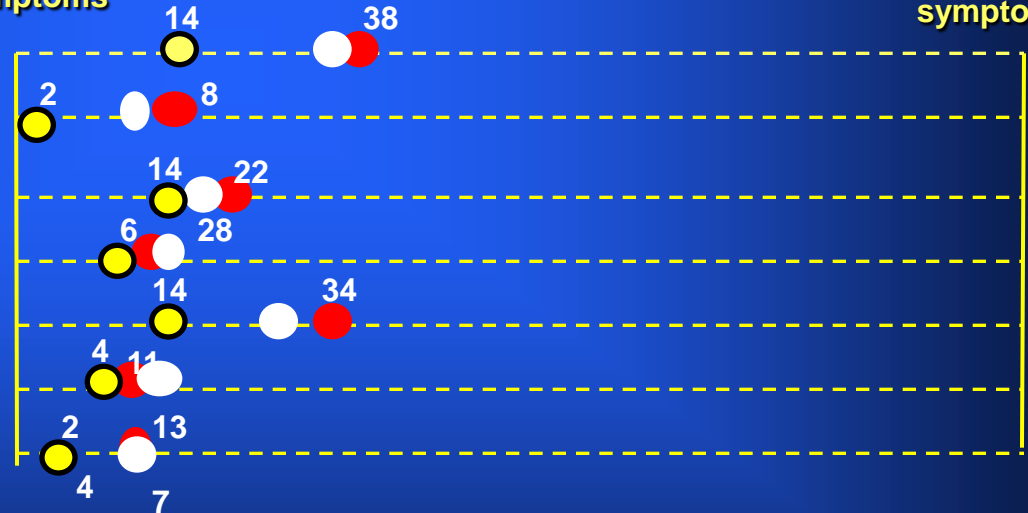


Symptoms scales

Fatigue
 Nausea and Vomiting
 Pain
 Dyspnea
 Insomnia
 Appetite loss
 Constipation

0 = No symptoms

100 = Many symptoms



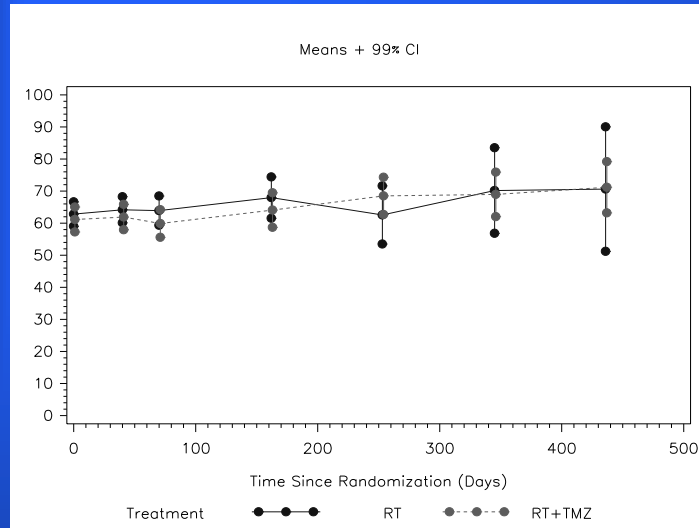
● Healthy women (50-59 years). (Schwarz et al. Eur J Cancer, 2001)

● Glioblastoma patients baseline (Bottomley et al 2005)

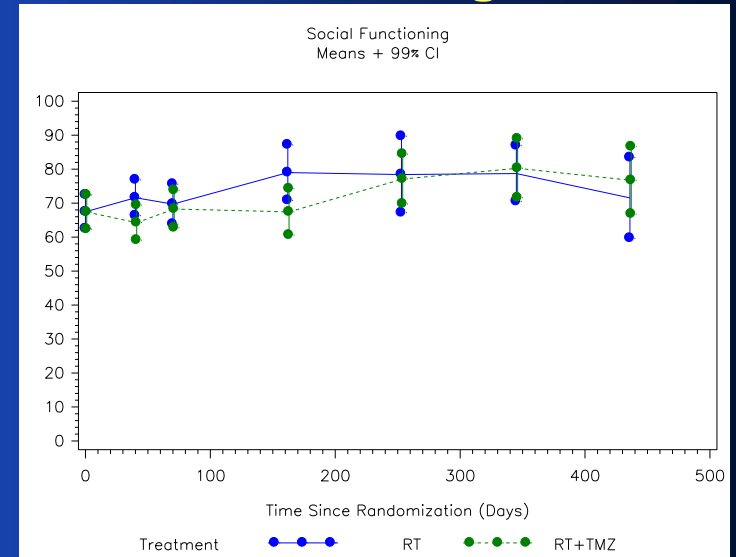
● Glioblastoma patients three months post treatment with RT/ temozolomide (Bottomley et al 2005)

Key message: no difference between arms

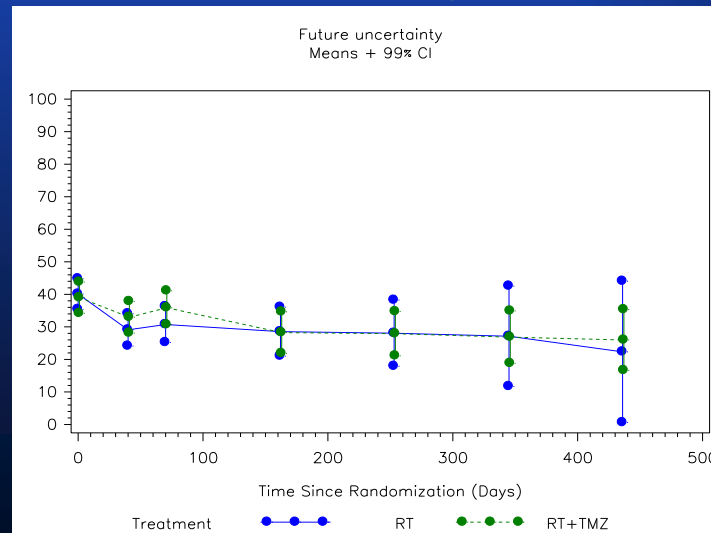
Global QOL scale over time



Social Functioning over time



Future Uncertainty over time



Conclusions

- Baseline QOL in GBM: Major impairment
- No negative impact of concomitant/adjuvant TMZ on QOL during treatment
- RT with concomitant and adjuvant TMZ :
 - **more** effective than standard treatment
 - **safe**
 - **no** detrimental effect on QOL
- EMEA/FDA approved this drug for GBM based on this trial (clinical data)