Study Spotlight INTRAGO II: IORT in newly diagnosed glioblastoma - multicentre, randomised, phase 3 trial with 314 patients

Seeing beyond

Radiotherapy (RT) added to standard of care (SOC) does not improve clinical outcomes, questioning the general value of further local dose intensification.

Title
Dose escalation with intraoperative radiotherapy in newly diagnosed glioblastoma (INTRAGO-II): an open-label, multicentre, randomised, controlled, phase 3 trial

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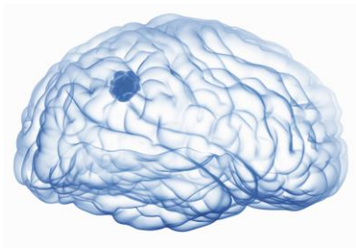
Methodology



Study Design

To evaluate whether additional intraoperative radiotherapy (IORT) compared to SOC improves outcomes in patients with newly diagnosed glioblastoma. 314 randomised patients, 298 patients with complete follow-up (161 IORT arm; 137 control arm) in multicenter setting of 18 sites.

Treatment

Patients in IORT arm received surgery + IORT dose of 20-30 Gy, patients in control arm received surgery alone. Both groups then received radio-chemotherapy (EBRT 60 Gy + temozolomide) and adjuvant chemotherapy with temozolomide. Median follow-up: 17.2 months.

Results

Adding further local radiotherapy to the SOC does not improve oncological outcomes

1. Overall survival (OS): 17.7 months
   (vs. 18.7 months in control arm); Fig. 1
2. Progression-free survival (PFS): 11.0 months
   (vs. 11.4 months in control arm); Fig. 2
3. Local recurrence (LR): 72%
   (vs. 71% in control arm; LR was main pattern of failure in both groups)
4. Grade 3-4 adverse events:
   - › Seizure: 13% (vs. 7% in control arm)
   - › Radiation necrosis 7% (vs. 2% in control arm)
   - › Thrombocytopenia 4% (vs. 8% in control arm)
   - › Muscle weakness 7% (vs. 14% in control arm)

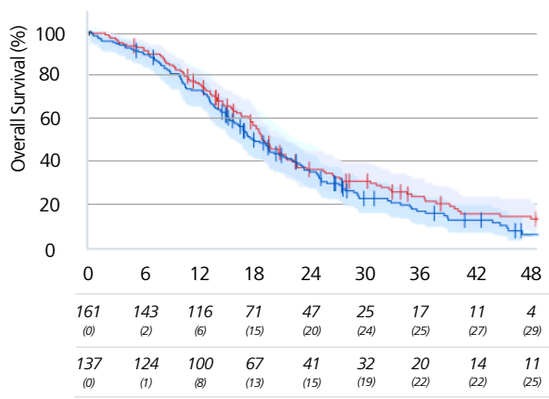


Fig. 1: Overall survival (shaded areas represent the 95% confidence intervals; vertical dashed lines represent censored patients)

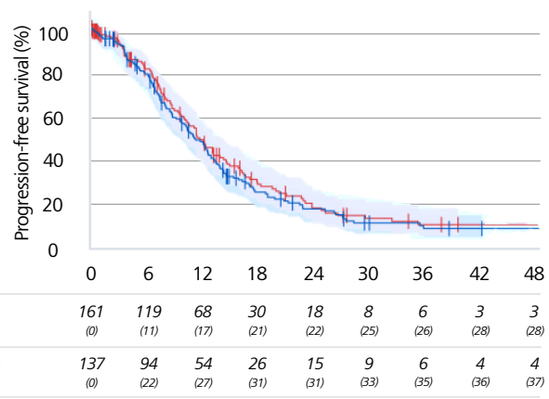


Fig. 2: Progression-free survival (shaded areas represent the 95% confidence intervals; vertical dashed lines represent censored patients)

Conclusion

- Adding an immediate, targeted high dose of RT to the SOC does not improve oncological outcomes or local tumor control
- Further intensification of local radiation dose (regardless of RT method) is unlikely to improve outcomes in resectable glioblastoma

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