Gemelli

Fondazione Policlinico Universitario A. Gemelli
Università Cattolica del Sacro Cuore

ART
Advanced Radiation Therapy


# What is the impact of high dose radiotherapy on survival and neurocognitive functions in naïve glioblastoma? A long term results of a prospective phase II study.

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***Il sottoscritto  Francesco Beghella Bartoli***

*ai sensi dell'art. 3.3 sul Conflitto di Interessi, pag. 17 del Reg. Applicativo dell'Accordo Stato-Regione del 5 novembre 2009,*

dichiara

*che negli ultimi due anni NON ha avuto rapporti diretti di finanziamento con soggetti portatori di interessi commerciali in campo sanitario*



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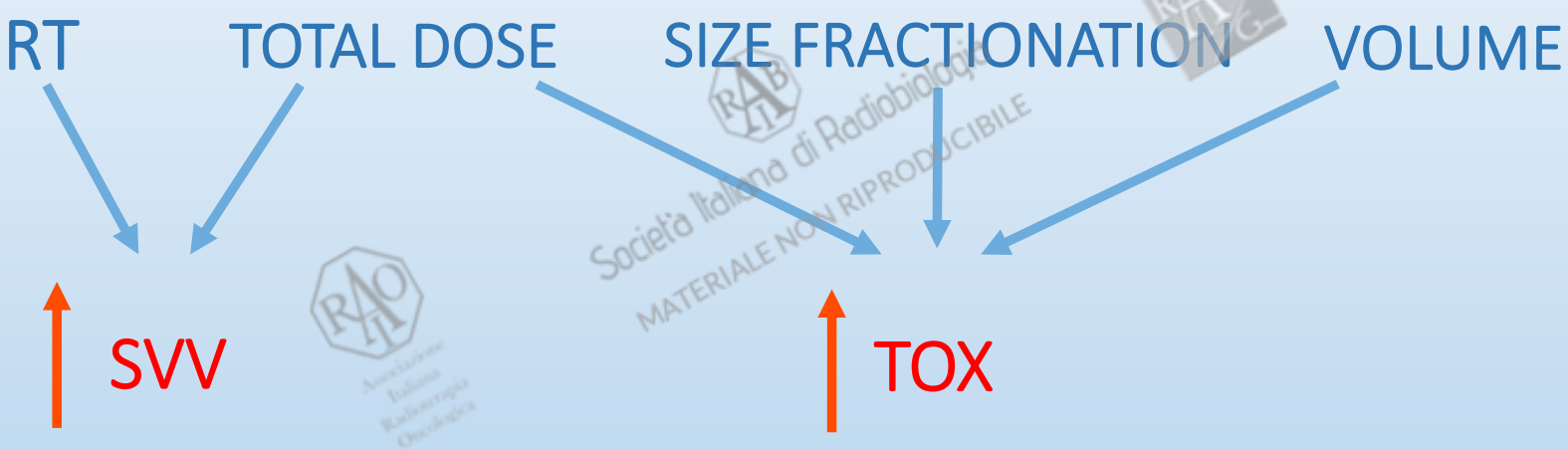
# BACKGROUND




**BTSG** 69-01

**BTSG** 72-01

**RTOG 74-01**

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# BACKGROUND

CLINICAL INVESTIGATION Brain

RELATIONSHIP BETWEEN NEUROCOGNITIVE FUNCTION AND QUALITY OF LIFE AFTER WHOLE-BRAIN RADIOTHERAPY IN PATIENTS WITH BRAIN METASTASIS

JING LI, M.D., PH.D.,* SOREN M. BENTZEN, PH.D., D.SC.,* JIALIANG LI, PH.D.,†
MARKUS RENSCHLER, M.D.,‡ AND MINESH P. MEHTA, M.D.*

**Neurocognitive function and QOL are correlated**. Neurocognitive function scores from previous visits are predictive of QOL. **Neurocognitive function deterioration precedes QOL decline**. The sequential association between NCF and

**A prospective study on neurocognitive effects after primary radiotherapy in high-grade glioma patients**

**Raphael Bodensohn[1] · Stefanie Corradini[1] · Ute Ganswindt[1] · Jan Hofmaier[1] · Oliver Schnell[2] · Claus Belka[1,3,4] · Maximilian Niyazi[1,3,4]**

HGG patients showed a marked decline in neurocognitive functioning in the course of their disease. **Patients with tumor progression performed worse on neurocognitive**

## The course of neurocognitive functioning in high-grade glioma patients[1]

Ingeborg Bosma,[2] Maaike J. Vos, Jan J. Heimans,[3] Martin J.B. Taphoorn, Neil K. Aaronson, Tjeerd J. Postma, Henk M. van der Ploeg, Martin Muller, W. Peter Vandertop, Ben. J. Slotman, and Martin Klein

**Changes in neurocognitive functioning and quality of life in adult patients with brain tumors treated with radiotherapy**

**Silvia Scoccianti · Beatrice Detti · Samantha Cipressi · Alberto Iannalfi · Ciro Franzese · Giampaolo Biti**



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# AIMS/METHODS

Primary endpoint:

- **Neurocognitive function evaluation**

Secondary endpoints:

- Overall Survival (OS)
- Progression free survival (PFS)

**CRITERY ELIGIBILITY**

- SVV ≥ 14,6 mo
- CTV ≤ 8 cm
- GBM
- Patients (≥18 yrs)



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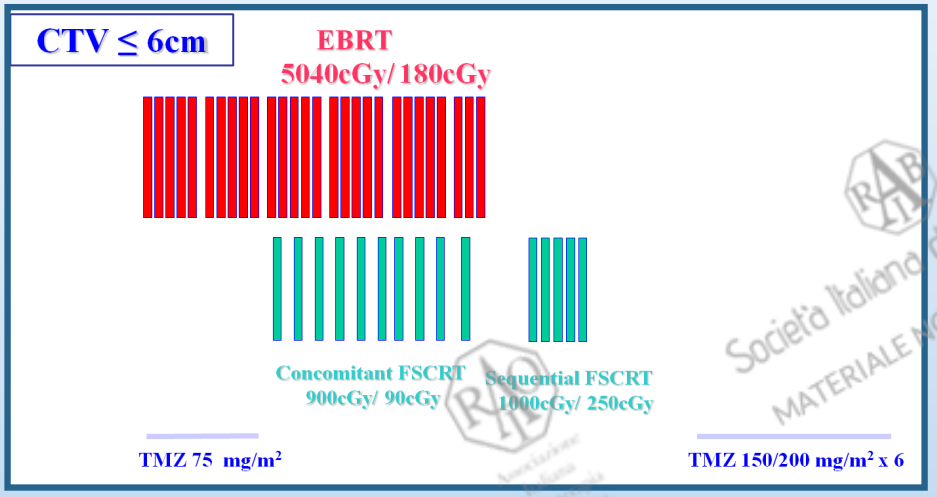
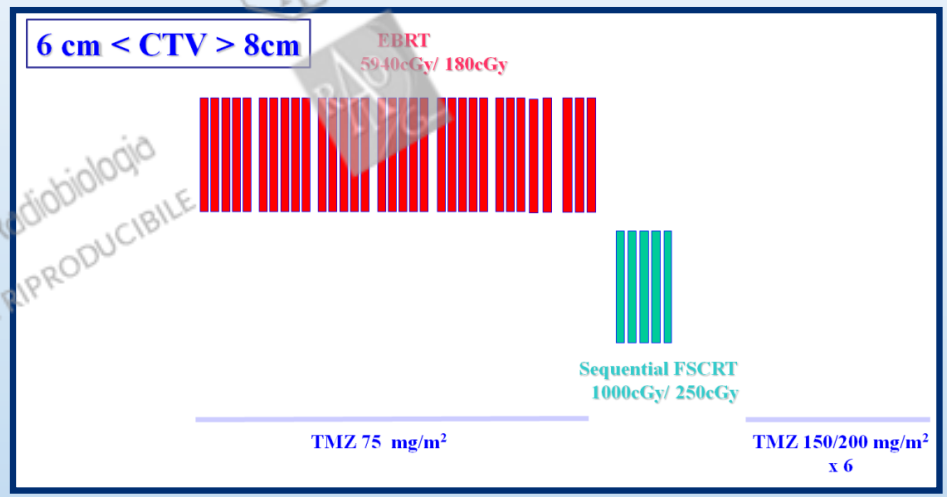
# METHODS






**Total dose: 6940 cGy**

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# METHODS

**Patients' characteristics**

| | Group A n=22 | Group B n=16 |
|---|---|---|
| Age (years) | | |
| • Median | 54 | 56 |
| • Range | 34-72 | 25-65 |
| Sex (n) | | |
| • Male | 13 | 10 |
| • Female | 9 | 6 |
| Type of surgery (n) | | |
| • Subtotal resection | 16 | 10 |
| • Total resection | 6 | 6 |
| RPA class (n) | | |
| • I | 4 | 2 |
| • III | 5 | 4 |
| • IV | 13 | 10 |

**OS ≥ 14.6 mth**



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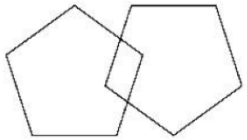
# METHODS

## The Mini-Mental State Exam

Patient_____ Examiner _____ Date_____

| Maximum | Score | |
|---|---|---|
| | | **Orientation** |
| 5 | ( ) | What is the (year) (season) (date) (day) (month)? |
| 5 | ( ) | Where are we (state) (country) (town) (hospital) (floor)? |
| | | **Registration** |
| 3 | ( ) | Name 3 objects: 1 second to say each. Then ask the patient all 3 after you have said them. Give 1 point for each correct answer. Then repeat them until he/she learns all 3. Count trials and record. Trials _____ |
| | | **Attention and Calculation** |
| 5 | ( ) | Serial 7's. 1 point for each correct answer. Stop after 5 answers. Alternatively spell "world" backward. |
| | | **Recall** |
| 3 | ( ) | Ask for the 3 objects repeated above. Give 1 point for each correct answer. |
| | | **Language** |
| 2 | ( ) | Name a pencil and watch. |
| 1 | ( ) | Repeat the following "No ifs, ands, or buts" |
| 3 | ( ) | Follow a 3-stage command: "Take a paper in your hand, fold it in half, and put it on the floor." |
| 1 | ( ) | Read and obey the following: CLOSE YOUR EYES |
| 1 | ( ) | Write a sentence. |
| 1 | ( ) | Copy the design shown. |



_____ Total Score

ASSESS level of consciousness along a continuum _____

Alert Drowsy Stupor Coma



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# RESULTS

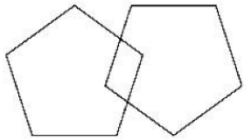
**11/38pts**

**OS ≥ 14.6 mth**

**The Mini-Mental State Exam**

Patient_____ Examiner _____ Date_____

| Maximum | Score | | |
|---|---|---|---|
| | | **Orientation** | |
| 5 | ( ) | What is the (year) (season) (date) (day) (month)? | TS: 10 |
| 5 | ( ) | Where are we (state) (country) (town) (hospital) (floor)? | TS: 9,6/10 |
| | | **Registration** | |
| 3 | ( ) | Name 3 objects: 1 second to say each. Then ask the patient all 3 after you have said them. Give 1 point for each correct answer. Then repeat them until he/she learns all 3. Count trials and record. Trials _____ | TS: 3 / TS: 3/3 |
| | | **Attention and Calculation** | |
| 5 | ( ) | Serial 7's. 1 point for each correct answer. Stop after 5 answers. Alternatively spell "world" backward. | TS: 5 / TS: 4,1/5 |
| | | **Recall** | |
| 3 | ( ) | Ask for the 3 objects repeated above. Give 1 point for each correct answer. | TS: 3 / TS: 2,2/3 |
| | | **Language** | |
| 2 | ( ) | Name a pencil and watch. | |
| 1 | ( ) | Repeat the following "No ifs, ands, or buts" | |
| 3 | ( ) | Follow a 3-stage command: "Take a paper in your hand, fold it in half, and put it on the floor." | TS: 8 / TS: 8/8 |
| 1 | ( ) | Read and obey the following: CLOSE YOUR EYES | |
| 1 | ( ) | Write a sentence. | |
| 1 | ( ) | Copy the design shown. | TS: 1 / TS: 0,9/1 |



____ Total Score — TS: 30 / TS: 27,9/30

ASSESS level of consciousness along a continuum _____

Alert Drowsy Stupor Coma

| 5 pts Without recurrence | 6 pts With recurrence |
|---|---|
| TS: 28,9 | TS: 25,7 |
| P value= 0,02 | |

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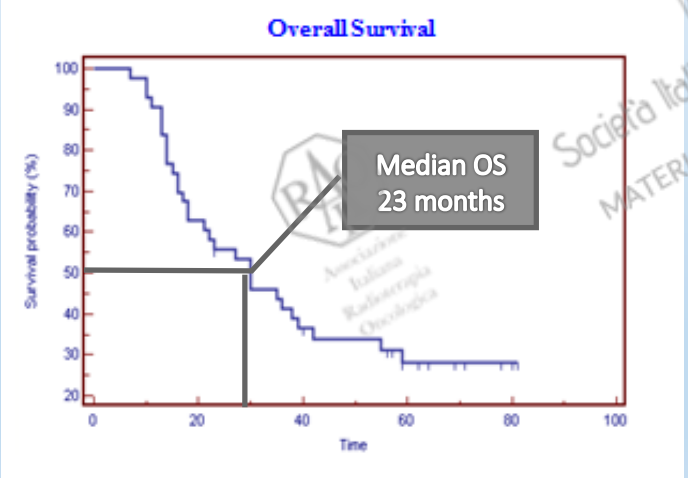
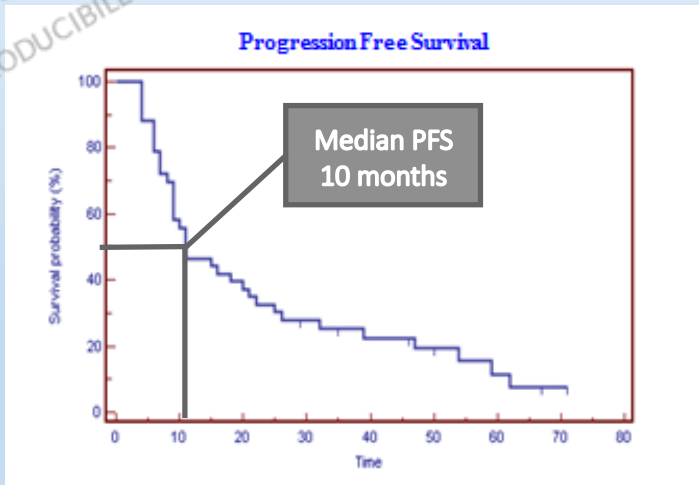
# RESULTS

| Tot: 38 pts | M: 23 (60%) | F: 15 (40%) |
|---|---|---|
| Median Age | 56 years (range 25-72 yrs) | |
| Median FUP | 77 months (25-87 mo) | |



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# Limitations

- Lack of baseline evaluation
- Sample size



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# Take home message

- Better outcome when **high doses** are used in combination with TMZ, without an increase of toxicity (no detrimental in NCF were observed)

- Tumor progression, may be the most important factor for the neurological deterioration

# Grazie per l’attenzione