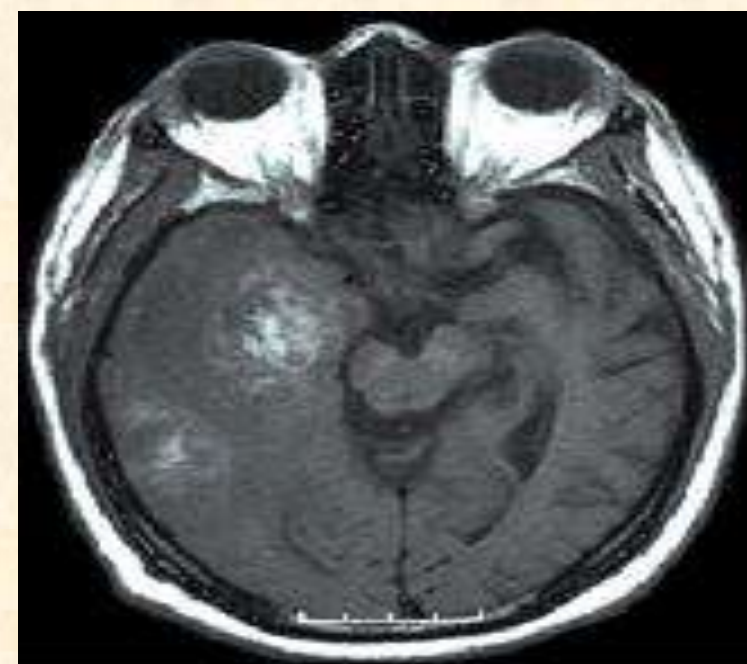
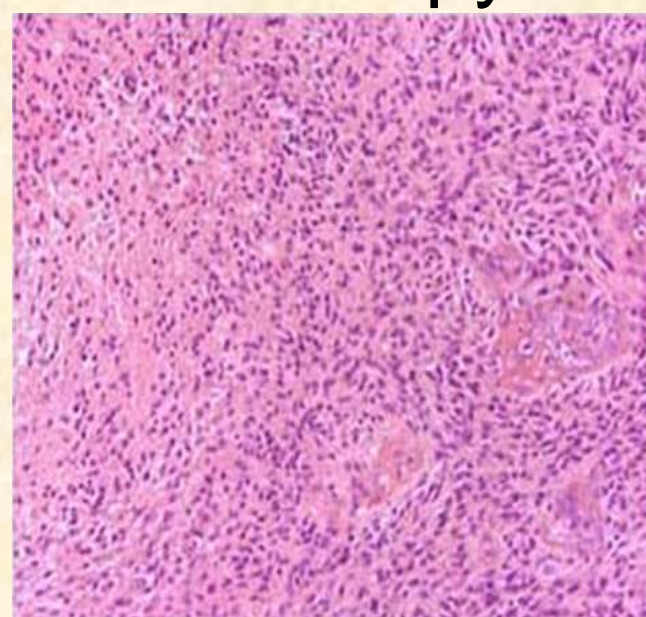


# Phase II Trial of Hyperbaric Oxygenation in Conjunction with Radiotherapy and Temozolomide in Adults with Newly Diagnosed Glioblastomas

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## Glioblastoma Facts

Heterogenous mixture of poorly differentiated neoplastic astrocytes  
GBM accounts for 15% of all intracranial neoplasm  
incidence of 4-5/100,00  
Second leading cause of cancer deaths in patients under 35 and fourth in patients under 54  
Mean survival 12-14 months and 2 year survival is approximately 26%  
Statistics have not changed despite new advances in surgery, radiation and chemotherapy



Due to diffusely infiltrative nature, surgical resection is not curative

Radiation therapy in combination with Temozolide is standard of care for newly diagnosed disease

No standard of care for recurrent disease  
Severe hypoxia within GBM is thought to play a role in their refractoriness to treatment

Ogawa et al published data indicating some improvement in survival with hyperbaric oxygen, prior to radiation with ACNU(nimustine) chemotherapy (17.3 month median survival)

## Clinical Protocol

### Inclusion Criteria

- Age greater than or equal to 18
- Histology confirmed newly diagnosed GBM
- Karnofsky score  $\geq 60$
- No significant co-morbidities or prior/concurrent antitumor therapy
- No Contraindications for Hyperbaric Oxygen Treatment

## Protocol

- Temozolomide 75mg/m<sup>2</sup>/day for 42 consecutive days
- Radiotherapy over 30 days for total dose of 6000cGy in (30) 200cGy fractions
- Hyperbaric Oxygen at 3.0 ATA for 30 minutes at pressure prior to each session of radiotherapy
- No more than 15 minute delay from exiting chamber to receiving radiation

## Winthrop University Hospital Hyper baric Unit



## Study Population Demographics

32 Patients enrolled beginning 6/2009  
19 Male  
13 Female  
Age Range 28-80  
Mean Age 62.5  
25/32 completed HCRT  
23 subjects evaluated

## Outcomes

Median survival 14.9 months  
Longest survival time to date 31.9 months  
12 month survival=82.6%  
18 month survival=43.4%  
24 month survival=34.8%

## Conclusions

Hyperbaric therapy in conjunction with radiation and chemotherapy is well tolerated without significant increased risk to adults with glioblastomas over current standard of care. Due to the small sample size of this study larger randomized trials are needed

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