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Outcome of High Grade Gliomas–An Institutional Experience

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ABSTRACT

Objective: In this study we evaluated the prognostic factors, dosimetry and survival outcome of high grade gliomas receiving radiotherapy with concurrent temozolomide and with or without adjuvant temozolomide. **Materials and Methods:** Eighty patients with high grade gliomas were treated with concurrent chemoradiation post operatively. 27 patients received 3D Conformal Radiotherapy, 25 received Intensity Modulated Radiotherapy and 28 were treated with Rapid arc. Temozolomide 75mg/m2/d seven days a week was given concurrently with radiation (60Gy in 30 fractions) followed by 6 cycles of adjuvant Temozolomide with a dose of 150mg/m2/d for 5 days in every 28 days. Primary end point was overall survival and secondary end point was effect of radiation technique on overall survival and dose to organs at risk. **Results:** All patients completed concurrent chemoradiation but only 52 patients completed 6 months course of adjuvant chemotherapy. Median age was 52.5 years; The prognostic factors important for overall survival are at least 6 cycles of adjuvant temozolomide ($p<0.0001$) and mean dose to normal brain <30 Gy (p-0.022). Median overall survival was 6 months. The median survival for patients who completed 6 months of adjuvant chemotherapy and those who did not was 12 months and 3 months respectively. Survival at 12, 18 and 24 months were 24.5%, 13.2% and 11.3% respectively for patients treated with high precision radiotherapy. One year survival in 3DCRT group was 3.7%. Mean dose to normal brain was 28.7Gy in 3DCRT, 23.9Gy in high precision technique respectively. **Conclusion:** Reduced doses to normal brain with high precision techniques and improved survival in our patients receiving radiotherapy with concurrent temozolomide & adjuvant 6 cycles of temozolomide.

Key words: Glioma, Glioblastoma, Radiotherapy, Temozolomide, Concomitant, Adjuvant, Survival.

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INTRODUCTION

High grade gliomas account for 50% of primary malignant tumors, glioblastoma multiforme (GBM) being most common.[1] GBM is one of the most aggressive tumors afflicting human body with median survival of one year.[1,2] Earlier, standard treatment included surgery in the form of maximal safe resection and post-operative radiotherapy (PORT). A meta-analysis based on 12 randomized trials showed a small survival benefit (6% in the one year survival rate, from 40% to 46%) from the addition of alkylating agents.[3] After the publication of phase III randomized trial, by Stupp *et al.*,[4] an oral alkylating agent temozolomide used concomitantly with PORT, followed by adjuvant temozolomide significantly improved median survival from 12.1 months to 14.6 months. Since then radiotherapy plus concomitant and adjuvant temozolomide has become the standard of care in newly diagnosed GBM.

High grade gliomas are usually large at the time of diagnosis. This predisposes large volume of normal brain to high doses of radiation during postoperative radiation therapy. High precision techniques like Intensity Modulated Radiotherapy (IMRT) reduces high dose to normal brain thus reducing neuro-cognitive effects in long term survivors.[1,5,6] In this study we evaluated the prognostic factors, dosimetry and survival of patients with grade III & IV newly diagnosed primary brain tumors.

MATERIAL AND METHODS

Eighty patients of Grade III & IV who were treated at a tertiary cancer centre, from January 2011 to December 2014, were analyzed retrospectively.

Primary Endpoint

Overall Survival (OS), defined as time from start of radiotherapy to last follow up or death.

Patient characteristics

The clinical characteristics are given in Table 1. Age ranged from 22 to 72 years, with median age of 52.5 years. There were 57 males & 23 females, frontal lobe tumors being most common.

Surgery

All patients underwent surgical resection and had confirmed diagnosis of either grade III or grade IV gliomas (WHO classification of tumors of Central Nervous System, 2007)

Radiation Therapy Treatment

Post-operative radiotherapy was started within 2-3 weeks of surgery. Treatment was delivered on Varian Clinac iX Linear accelerator using 6 MV x-rays.

Thermoplastic mask was made for each patient. Computed Tomography (CT) simulation was done for radiation therapy planning. A total dose of 6000 cGy @ 200 cGy per fraction over 6-7 weeks was delivered in two phases. In phase one, radiation dose of 5400 cGy delivered to post-operative tumor bed, residual disease defined by CT/MRI fusion with T2 & FLAIR images plus surrounding edema with a margin of 2 cm (CTV1). PTV1 was 0.5 cm margin from CTV1. In second phase, a boost dose of 600 cGy was delivered to contrast enhancing tumor plus 2 cm margin (CTV2). PTV2 was 0.5 cm from CTV2. The normal tissues delineated included brain stem, optical structures, spinal cord, normal brain (i.e. whole brain-PTV1). The acceptable coverage was defined as D95 (dose received by 95% of the PTV) of at least 95% of the prescribed dose.

27 patients received 3D Conformal Radiotherapy, 25 received Intensity Modulated Radiotherapy (IMRT) and 28 were treated with Rapid Arc technique.

Chemotherapy

All patients received temozolomide concurrently during the course of radiotherapy at a dose of 75 mg/m^2/day, 7 days per week, one hour before radiation with anti-emetics. At one month after completion of radiation, 52 patients received 6 cycles of adjuvant temozolomide (dose of 150 mg/m^2/day) for 5 days in every 28 days.

Follow Up

The patients who received adjuvant temozolomide were assessed at every 4 weeks. Those who discontinued temozolomide were reviewed every three monthly or sooner as and when the patient reported.

Statistical Analysis

Ratio and interval scale data was summarized as mean and standard deviation whereas nominal/categorical scale data as proportions (%). Shapiro–Wilk test was used to assess normality of data. For univariate analysis, Unpaired't' test & ANOVA was used between group comparison of ratio and interval scale data. Significant variables in univariate analysis were entered in multivariate regression analysis. Probability of enter variable in model was kept if $p<0.05$ and of remove variable if $p>0.1$ with backward method. Significant predictors of survival were used for Regression Equation.

Kaplan-Meier survival analysis was done and Log Rank (Mantel-Cox) test was used comparison of survival w.r.t. different factors 'p' value <0.05 was considered as statistically significant. Medcalc 12.2.1.0 version software was used for all statistical calculations.

RESULTS

Survival

Median follow up was 6 months (range: 1-36 months). Median overall survival was 6 months (95% confidence interval, [CI], 5.4-6.5). One-year survival rate was 17.5%. Median overall survival was 12 months (95% CI, 9.8-14.1) for patients who completed 6 cycles of adjuvant temozolomide and 3 months (95% CI, 1.7-4.2) for patients not completing 6 cycles (0-5 cycles) [Figure 1].

Median overall survival was 7 months (95% CI, 5.1-8.8) for patients who received high precision radiotherapy and 3 months (95% CI, 1.7-4.2) for patients who were treated with 3DCRT technique. Survival at 12, 18 & 24 months was 24.5%, 13.2%, 11.3% respectively for patients treated by high precision technique. One-year survival was 3.7% in 3DCRT group [Figure 2].

Prognostic Factors

On univariate analysis, patients who had KPS≥70, completing 6 cycles of adjuvant temozolomide, [(PTV1/whole brain) X100] <34% (i.e. less than 1/3rd volume), mean dose to normal brain <30 Gy had better survival [Table 2]. The Kaplan-Meier survival curves are shown in Figure 1. A multivariate Cox regression model was used to test the effect of these variables on overall survival. The prognostic factors important for overall survival are at least 6 cycles of adjuvant temozolomide (95% CI, 9.8-14.1, $p<0.0001$) and mean dose to normal brain <30 Gy (95% CI, 5.4-6.5, p-0.022). Dosimetric analyses shown in Table 3. Distribution of patients based on prognostic variable are shown in Table 4.

DISCUSSION

Achieving long term survival in patients of glioblastoma of high-grade gliomas is not possible due to its aggressive nature.[7] Despite advances in surgery, new chemotherapeutic agents and techniques in radiotherapy the prognosis of high-grade gliomas is still poor.

Table 1. Patient Characteristics

PATIENT CHARACTERISTIC	NO.OF PATIENTS	% OF TOTAL NO. OF PATIENTS
Age(years)		
Mean	49.2	
Median	52.5(range22-72)	
Sex		
Male	57	71.25
Female	23	28.75
History of Seizzures		
Yes	49	61.25
No	31	38.75
Karnofsky Performance Status(KPS)		
<70	21	26.25
≥70	59	73.75
Grade		
III	35	43.75
IV	45	56.25
Tumor size(cm)		
<6 cm	66	82.5
≥6 cm	14	17.5
Location		
Frontal Lobe	32	40
Temporal Lobe	17	21.25
Parietal lobe	24	30
Occipital Lobe	4	5
Midline SOL	3	3.75
Laterality		
Left	43	53.75
Right	34	42.5
Midline	3	3.75
Extent of Surgery		
Subtotal Resection	48	60
Total Resection	32	40
Concurrent TMZ*		
Yes	80	100
Adjuvant TMZ		
Yes (6 cycles)	52	65
No (0-5 cycles)	28	35
Discontinuation of TMZ	28	
Reason – Disease progression	14	17.5
Decision by patient	7	8.7
Death	7	8.7
Radiotherapy technique		
3DCRT**	27	33.75
IMRT#	25	31.25
RAPID ARC##	28	35

*TMZ: Temozolomide, **3DCRT:3-dimensional conformal radiotherapy, #IMRT: Intensity Modulated Radiotherapy, ##RA: Rapid Arc,

A randomized trial by the European Organization for Research and Treatment of Cancer (EORTC) and the National Cancer Institute of Canada (NCIC) demonstrated that concomitant radiotherapy plus continuous daily TMZ followed by adjuvant TMZ significantly prolonged the survival in patients with glioblastoma. Patients with newly diagnosed glioblastoma were randomly assigned to receive radiotherapy alone (a 2 Gy daily fraction, 5 days per week for a total dose of 60 Gy) or radiotherapy plus continuous daily temozolomide (75 mg/m^2 daily dose, 7 days per week, during the course of radiotherapy), followed by 6 cycles of adjuvant TMZ (150-200 mg/m^2, for 5 days during each 28-day cycle). The median survival was 14.6 months for the radiotherapy plus temozolomide group and 12.1 months for the radiotherapy alone group (P <0.001). The 2-year survival rate was 26.5% for the combined treatment group.[4]

Table 2. Prognostic variables (univariate analysis)

PATIENT CHARACTERISTIC	No. of patients	Univariate analysis ('p' value)
Age(years)		
<50	36	0.392
>50	44	
Sex		
Male	57	0.838
Female	23	
History of Seizures		
Yes	49	0.245
No	31	
Karnofsky Performance Status(KPS)		
<70	21	**0.024**
≥70	59	
Grade		
III	35	0.598
IV	45	
Site		
Left	43	0.777
Right	34	
Midline	3	
Tumor size(cm)		
<6 cm	66	0.386
≥6 cm	14	
Location		
Frontal Lobe	32	0.378
Others	48	
Location		
Parietal Lobe	24	0.357
Others	56	
Extent of Surgery		
Subtotal Resection	48	0.961
Total Resection	32	
Adjuvant TMZ*(6 cycles)		
Yes	52	**<0.001**
No	28	
RT** Technique		
3DCRT#	27	**<0.001**
IMRT##/RA###	53	
[(PTV1$/whole brain volume)x100]		
<34%	57	**<0.046**
≥34 %	23	
Dmean$$ of Normal Brain(whole brain volume – PTV1)	63	**0.002**
<30 Gy	17	
≥30 Gy		

*TMZ: Temozolomide; **RT: Radiotherapy, #3DCRT:3-dimensional conformal radiotherapy, ##IMRT: Intensity Modulated Radiotherapy, ###RA: Rapid Arc, $PTV1: planning target volume of phase I, $$Dmean: Mean Dose

Patients with glioblastoma containing a methylated MGMT promoter region showed an improved survival compared to those who did not have a methylated MGMT promoter region.[8]

Erpolat *et al.*,[9] also found that patients completing 6 cycles of adjuvant temozolomide therapy had significantly better outcome. They observed a median survival of 22.7 months for patients completing 6 cycles of adjuvant temozolomide as compared to 12 months for patients not completing 6 cycles of therapy and this difference was statistically significant (P value 0.011). In our study, all patients received Temozolomide 75 mg/m^2 everyday with radiotherapy as recommended by the EORTC/NCIC trial. We evaluated the benefit from the addition of adjuvant temozolomide to concomitant therapy and the determination of its efficacy at certain cycles. Over-

Table 3. Dosimetry of 3DCRT and High precision techniques

STRUCTURE	3DCRT*	IMRT**/RA***
PTV1(vol)#	442.8 ± 152.4	387.3 ± 161.7
Max Dose (%)	105.9 ± 2.0	107.2 ± 1.2
Min Dose (%)	85.5 ± 9.54	89.9 ± 4.6
Mean Dose (%)	100.4 ± 1.65	102.1 ± 0.9
Normal Brain##		
Mean Dose(Gy)	28.7 ± 6.9	23.9 ± 5.1
Brain Stem		
Max Dose(Gy)	42.5 ± 17.1	47.6 ±14.8
Right Eye		
Max Dose(Gy)	8.98 ± 8.7	18.8 ±13.6
Left Eye		
Max Dose(Gy)	9.3 ± 10.1	20.4 ± 15.0

*3DCRT:3-dimensional conformal radiotherapy, **IMRT: Intensity Modulated Radiotherapy, ***RA: Rapid Arc, #PTV1: planning target volume of phase I, ##Normal Brain: includes all brain tissue excluding PTV1.

Table 4. Prognostic variables, radiotherapy technique

	IMRT+ RAPID ARC (n,%)	3DCRT (n,%)
KPS		
<70	13(24.5)	8(29.6)
≥70	40(75.4)	19(70.3)
Dose		
<60 Gy	13(24.5)	7(25.9)
≥60 Gy	40(75.4)	20(74)
Adjuvant TMZ		
6 cycles	36(67.9)	16(59.2)
0-5 cycles	17(32)	11(40.7)
Mean dose of normal brain		
<30 Gy	47(88.6%)	16(59.2)
≥30 Gy	6(11.3%)	11(40.7)
PTV1/whole brain		
<34%	43(81.1)	14(51.8)
≥34%	10(18.8)	13(48.1)

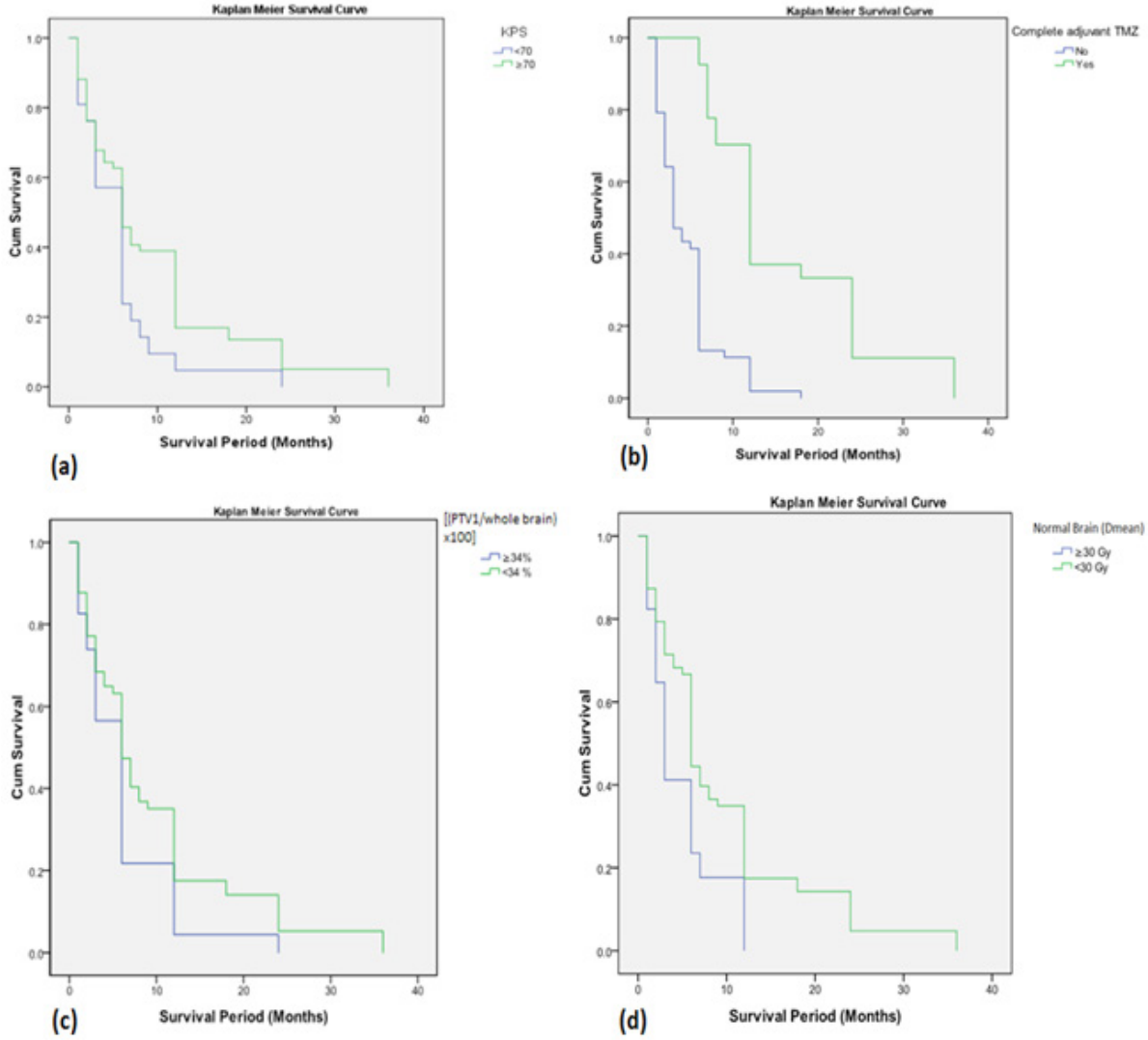

Figure 1: Overall survival by (a) KPS, (b) Complete adjuvant Temozolomide (6 cycles – yes; 0-5 cycles – no) (c) [(PTV1/Whole Brain) X100] (d) Mean dose to Normal Brain.

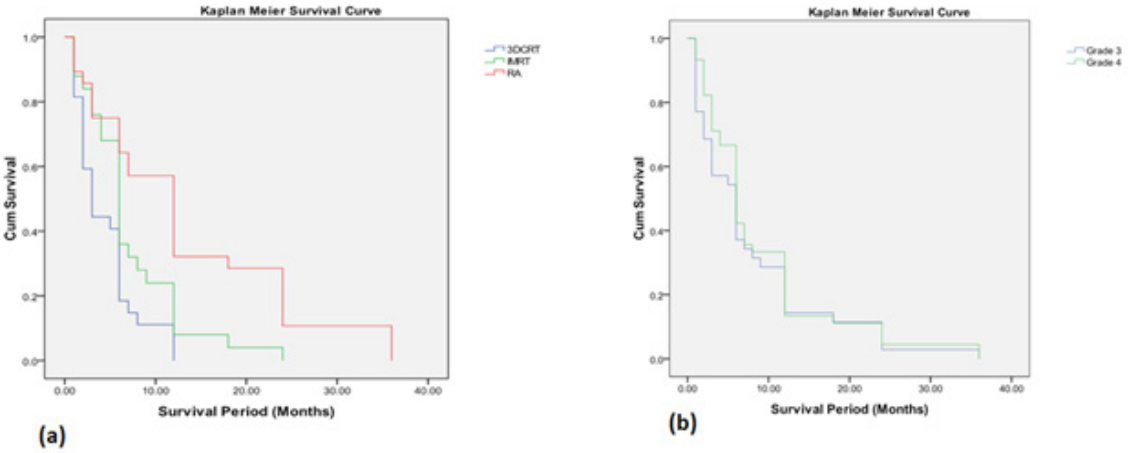

Figure 2: Overall Survival by (a) Radiotherapy technique (b) Grade 3 & 4

all survival was analyzed based on the comparison of the two groups, those received 6 cycles and those received 0-5 cycles of adjuvant temozolomide. There is significant increase in overall survival in patients receiving 6 cycles of adjuvant temozolomide (12 months vs 3 months, p<0.001). Both univariate and multivariate analysis show that at least 6 cycles of adjuvant temozolomide improved overall survival. The median overall survival was 14.6 months in Stupp *et al.*,[4] and 13.4 months in Athanassiou *et al.*,[10] in patients who received radio chemotherapy.

Curran *et al.,* reported that the prognosis of malignant gliomas might be predicted based upon clinicopathologic variables. Recursive partitioning analyses of the prognostic factors identified the five major variables including age, tumor type, performance status, mental status and treatment (extent of surgery and radiation dose). According to this classification, patients with poor performance-mental status and /or advanced ages have poor survival when compared to young patients with good performance-mental status.[11]

In current study, univariate analysis was performed based on these variables and the important prognostic factors were KPS (<70 vs ≥70), adjuvant temozolomide (6 vs 0-5 cycles), [(PTV1/whole brain) X100] (<34% vs ≥34%) and mean dose of normal brain (<30 Gy vs ≥30 Gy).

The Recursive partitioning analyses (RPA) model developed by Curran *et al.*,[11] found median survival of 18 months in patients with GBM who were <50 years of age with KPS of 90. Lacroix *et al.,* analyzed 416 patients of GBM. Median survival for patients with KPS <70 was 8.8 months vs 11.2 months for those with KPS >70.[12] In another study by Lutterbach *et al.,* median survival was 8.8 months for patients with KPS >70 & 6.7 months for KPS <70.[13] In our study median survival was 6 months for KPS≥70.

We evaluated the effect of dosimetry on overall survival retrospectively. There has been a dramatic improvement in radiotherapy techniques in last 2 decades. IMRT has shown to improve the dose distribution to target volume and less dose to normal tissues as compared to 3DCRT techniques.[14] The outcomes of IMRT for dose escalation and critical organ sparing in prostate and head and neck cancer sites are encouraging.[15,16]

Our result has shown that OS improved with high precision techniques (IMRT & RAPID ARC) as compared to 3DCRT technique in high-grade gliomas. There was 4 months improvement in survival for patients treated with high precision than with 3DCRT (median survival 3DCRT-3 months, IMRT/RA-7 months p value <0.001, 95% CI 5.1-8.8). On subset analysis, Rapid Arc patients had better overall survival than with other high precision techniques (RA-12 months, IMRT-6 months). So overall there was 9 months and 6 months improved survival with RA and IMRT respectively as compared to 3DCRT. On dosimetric analysis 88.6% of patients received <30 Gy mean dose to normal brain in high precision group while 59.2% patients in 3DCRT group. On univariate analysis mean dose to normal brain had impact on median survival in our study. The patients receiving <30 Gy mean dose to normal brain had median survival of 6 months while those receiving ≥30 Gy had median survival of 3 months (p=0.002). It has also been validated in the literature that IMRT plans yield decreased dose to critical structures in brain and reduced dose of high radiation to normal brain[5,6] which results in reduced delayed toxicity like neuro-cognitive decline and radiation necrosis. So, high precision techniques yield less dose to normal brain thus reducing late radiation toxicities.

In the present series, mean volume of whole brain was 1272.97cc, mean volume of PTV1 was 415.05cc and mean volume normal brain (excluding PTV1) was 879.12cc. (In Eclipse treatment planning system, the segment model is designed for delineating naturally curved shapes. The model is not optimal for representing some geometrical shapes, such as sharp edges or miniscule structures. For instance, when creating rectangular segments, Eclipse rounds the corners of the rectangle) Thus, high-grade gliomas occupied approxi-

mately one third of the volume of normal brain. Therefore, a large volume of normal brain parenchyma was at risk of getting exposed to high doses of radiation while treating such tumors. In this study, patients who received full dose to <1/3rd of whole brain had better survival than those who received >1/3rd. The ratio of PTV1 to whole brain less than 1/3rd was 81.1% patients in high precision group and 51.8% in 3DCRT group.

A study by Narayana *et al.*,[6] which included 58 patients with high-grade gliomas who were treated with IMRT, attempted to address the potential clinical impact of IMRT. Mean dose to normal brain achieved for IMRT patients was 38.9 % of prescription dose vs 3DCRT 41.9 % of prescription dose (p=0.0004). With a median follow-up of 24 months, the overall survival was 36 months for anaplastic astrocytoma and 9 months for glioblastoma, respectively. In Anand *et al.*,[17] mean volume of PTV1 was 454.26cc and the mean volume of normal brain (excluding PTV1) was 912.78cc. Mean dose of radiation delivered to 67% volume of the normal brain was 26.7Gy. In present study mean dose to normal brain was 23.9 Gy for high precision patients and 28.7 Gy for 3DCRT patients.

CONCLUSION

In conclusion, the results of our study confirm the radiotherapy plus concomitant and adjuvant 6 cycles temozolomide yield encouraging outcomes in our population. High precision techniques reduce doses to normal brain

AKNOWLEDGEMENT

Nil

CONFLICT OF INTEREST

Nil

ABBREVIATIONS USED

GBM: Gliioblastoma multiforme; 3DCRT: 3dimensional conformal radiotherapy; IMRT: Intensity Modulated Radiotherapy; RA-Rapid Arc; OS: Overall Survival; WHO: World Health Organisation; CI-Confidence Interval; TMZ: Temozolomide; MGMT: O6- methylguanin- DNA- methyltransferase; KPS: Karnofsky Performance Status; RPA: Recursive Partitioning Analyses.

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