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## Hypofractionated radiation for pediatric diffuse intrinsic pontine glioma (DIPG) is non-inferior to conventional fractionation: a prospective randomized trial including 222 children

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Background: Pediatric diffuse intrinsic pontine glioma (DIPG) remains for the last decades as a dismal disease though of the rigorous attempts to improve results through adding chemotherapy, immunotherapy or target therapy in different combination, scheduling and intensity to the already established conventional radiation therapy. We previously reported that hypofractionated radiotherapy, in a dose of 39 Gy in 2.6 weeks, had similar clinical end-results to conventional 54 Gy in 6 weeks.

Aim of the work: to confirm the non-inferiority of hypofractionated to conventional fractionation in treating pediatric DIPG and to explore the optimum dose level for such treatment to achieve better overall (OS), progression-free survival (PFS) and toxicity profile.

Methodology: Tow hundred twenty-two children fulfilling the typical clinical and MR imaging features of DIPG were randomized into 3 groups:

1. Hypofractionated 39 Gy in 13 fractions (300 cGy/fraction),

2. Hypofractionated 45 Gy in 15 fractions (300 cGy/fraction) and

3. Conventional 54 Gy in 30 fractions (180 cGy/ fraction).

Results:

The distribution of patients' characteristics in the 3 groups were even and did not show any statistically significant differences. The median overall survival (OS) of all patients was 8.5 months (95% CI: 7.6 –9.4) while the progression-free survival (PFS) was 6.8 months (5.9 -7.6). The median OS of the 3 groups (39, 45 and 54 Gy) were 9.6 (7.6 -11.6), 7.7 (6.2 -9.3) and 8.6 (7.3 –9.9) months respectively. The 18-months OS for the 3 groups were 14.0  $\pm$  4.7%, 14.5  $\pm$  4.4% and 9.7 $\pm$  4.3% respectively revealing non-inferiority of either hypofractionated group to the conventional group. Furthermore, the median PFS in the 2 hypofractionated (39 and 45 Gy groups) were 8.0 months (6.4 -9.6) and 5.8 months (4.8 –6.9) respectively compared to 6.9 months (5.9 –8.0) for the conventional group. These PFS results of either hypofractionated group proved to be non-inferior to that of conventional fractionated group. The toxicity profile was similar in the 3 treatment groups.

Both median OS, PFS and the 18-months OS and PFS were not affected by the patient gender nor age. However, it was noticed that young patients (below 5 years old) had better treatment outcome (OS and PFS) though not statistically significant.

Conclusion:

Hypofractionated radiotherapy clinical outcome is non-inferior to conventional fractionation for the treatment of pediatric DIPG. It seems that no optimal dose level for hypofractionated radiotherapy of DIPG. These results may establish hypofractionated radiotherapy as the standard of care for such aggressive disease to minimize the burden on the child, the family and treating institution without jeopardizing the results of treatment including OS, PFS and toxicity.

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