Abstract

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Observational real-life study on regorafenib in recurrent glioblastoma: does dose reduction reduce toxicity while maintaining the efficacy?

Rudà R(#)(1)(2), Bruno F(#)(3), Pellerino A(3), Pronello E(3)(4), Palmiero R(3), Bertero L(5), Crasto S(6), Polo V(7), Vitaliani R(8), Trincia E(9), Internò V(10), Porta C(10)(11), Soffietti R(3).

Author information:
(1)Division of Neuro-Oncology, Department of Neuroscience, University and City of Health and Science Hospital, Turin, Italy. rudarob@hotmail.com.
(2)Department of Neurology, Castelfranco Veneto and Treviso Hospitals, Castelfranco Veneto, Italy. rudarob@hotmail.com.
(3)Division of Neuro-Oncology, Department of Neuroscience, University and City of Health and Science Hospital, Turin, Italy.
(4)Neurology Unit, Department of Translational Medicine, University of Eastern Piedmont, Novara, Italy.
(5)Pathology Unit, Department of Medical Sciences, University of Turin, Turin, Italy.
(6)LARC and RIBA MRI Services, Turin, Italy.
(7)Oncology Unit, Azienda Unità Locale Socio-Sanitaria (AULSS 2) Marca Trevigiana, Cà Foncello Hospital, Treviso, Italy.
(8)Division of Neurology, Cà Foncello Hospital, AULSS2 Marca Trevigiana, Treviso, Italy.
(9)Neuroradiology Unit, Cà Foncello Hospital, AULSS2 Marca Trevigiana, Treviso, Italy.
(10)Division of Medical Oncology, A.O.U. Consorziale Policlinico di Bari, Bari, Italy.
(11)Division of Medical Oncology, Department of Interdisciplinary Medicine, University of Bari Aldo Moro, Bari, Italy.
(#)Contributed equally

PURPOSE: In the phase 2 REGOMA trial, regorafenib improved overall survival, as compared with lomustine, in glioblastoma (GBM) patients at first progression after chemoradiation. Recently, some real-life trials showed similar impact on survival but a higher rate of adverse events than in REGOMA, thus raising concerns over tolerability. The aim of this study was to assess the efficacy and tolerability of a lower intensity regorafenib regimen.

PATIENTS AND METHODS: Regorafenib daily dose was gradually increased from 80 to 160 mg across the first 2 cycles. Progression-free survival (PFS) and overall survival (OS) were defined as time from regorafenib initiation and disease progression or death.

RESULTS: Sixty-six GBM patients were included. Median age was 60.0 years. Median PFS and OS following regorafenib were 2.7 and 7.1 months, respectively. Best RANO response to regorafenib were partial response (PR) in 10 (15.1%), stable disease in 17 (25.8%), and progressive disease in 39 (59.1%) patients. Forty-six (69.7%) patients presented adverse events of any grade, and 21 (31.8%) grade 3-4 toxicity. In a multivariable analysis, higher age and absence of MGMTp methylation were significantly associated with poorer disease control after regorafenib.

CONCLUSIONS: Our study is the largest observational real-life study on the use of regorafenib. Our lower intensity regimen proved as effective as the standard 160 mg daily schedule (mPFS and mOS being 2.7 vs 2.0 months and 7.1 vs 7.4 months in our study vs REGOMA, respectively). Moreover, we observed a higher rate of PRs as compared with REGOMA (15.0% vs 3.0%).

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