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A NON-INTERVENTIONAL STUDY OF OBINUTUZUMAB IN PATIENTS WITH PREVIOUSLY UNTREATED ADVANCED FOLLICULAR LYMPHOMA (URBAN): IMPACT OF COVID-19 PANDEMIC ON ENROLLMENT AND SAFETY

A. Pinto1, P. L. Zinzani2, L. Arcaini2, G. Gritti4, C. Patti5, E. Pennese6, S. De Lorenzo7, C. Piparo8, E. Guardalben9, M. Ladetto10
1Istituto Nazionale Tumori, Fondazione ‘G. Pascale’, IRCCS, Ematologia Oncologica, Naples, Italy, 2Università di Bologna, Istituto di Ematologia “Seràgnoli”, Bologna, Italy, 3Fondazione IRCCS Policlinico San Matteo, Divisione di Ematologia, Pavia, Italy, 4Ospedale Papa Giovanni XXIII, Ematologia, Bergamo, Italy, 5Azienda Ospedali Riuniti Villa Sofia-Cervello, Oncemematologia, Palermo, Italy, 6Ospedale Santo Spirito, Dipartimento di Oncologia ed Ematologia, Pescara, Italy, 7Azienda Ospedaliera Rilievo Nazionale (A.O.R.N.) S. Giuseppe Moscati, Ematologia, Avellino, Italy, 8Roche Spa, Clinical Operations, Monza, Italy, 9Roche Spa, Medical Affairs, Monza, Italy, 10Azienda Ospedaliera Santi Antonio e Biagio e Cesare Arrigo, Ematologia, Alessandria, Italy

Background. The introduction of new agents has improved the prognosis of follicular lymphoma (FL). Unfortunately, COVID-19 pandemic may have affected disease management.

Objective. The non-interventional, retrospective/prospective URBAN study is aimed to evaluate effectiveness and safety of Obinutuzumab-based treatment in real-life practice of patients with untreated advanced FL with FLIPI≥2. The study is ongoing in 46 sites in Italy. The objective of this interim analysis is to evaluate patient characteristics, potential changes in the management due to COVID-19 pandemic, preliminary efficacy at the end of induction (EOI) and safety data collected about 1 year after the first patient enrolled.

Methods. Participants should have received at least 2 cycles of Obinutuzumab-chemotherapy induction before the enrollment (retrospective part of the study). The study, launched in Sep-2019 includes 6-8 induction courses, 2-year maintenance with Obinutuzumab monotherapy, and 1-year follow-up period after the last Obinutuzumab administration. Two time periods have been analyzed:
Waldenström macroglobulinemia (WM) is a rare disease, accounting for less than 2% of non-Hodgkin’s lymphoma. Current data on the clinical and epidemiological characteristics of the disease are widely from European and American centers. Data on Brazilian WM patients are scarce in the literature, represented only by case reports.

This study aimed to retrospectively assess clinical features, treatment options and outcomes of patients diagnosed with WM from 1999 to 2017 at a single university center in Sao Paulo, Brazil.

Fifty patients met the eligibility criteria, 31 (62%) males with median age at diagnosis of 63.5 years (range 42-84). The median (IQR) values of blood tests at presentation were: hemoglobin 9.1g/dl (7.9-11), platelet 178.000/mm$^3$ (112-240), $\beta_2$M 3.6g/dl (2.6-5.0), calcium 9.1mg/dl (8.8-9.6), IgM 3495mg/dl (368-9759). Median time from diagnosis to start of treatment was 41 days (min-max, 0-966). IPSSWM-R was very low and low risk in 38%, while 42% of cases were high or very high risk. All but 3 patients (watch and wait) were treated. The following indications for treatment were available in 38 patients: anemia (71%), thrombocytopenia (26%), B symptoms (47%) and symptomatic neuropathy (8%) and hemolytic anemia (8%).

The main chemotherapy protocols for first-line therapy were: CVP (37.5%), chlorambucil (20.8%) and FC (10.4%). Overall response rate (ORR) was 45.7%, mainly partial remission (PR) (37.1%). Stable disease occurred in 28.5% and progressive disease in 25.7% of cases. Thirty-one patients (62%) received second-line therapy. The most prescribed protocols were CVP (n = 10), CHOP (n = 5), Fludarabine (n = 4), chlorambucil (n = 4) and FC (n = 3). PR was the commonest response (45%). The median follow-up time was 4.0 years (0-10, IQR). Estimated 4-year OS was 63% (CI 95%, 46-76), and 4-year PFS was 35% (CI 95%, 21-49).

Our study reflects a real-world experience of a rare disease in a public health university center in a middle-income country, with resource constrained limitations. Our study has limitations, mainly related to its retrospective design. Moreover, genotype test is not reimbursed and there is no approval for Rituximab, Bendamustine or Bruton tyrosine kinase inhibitors in Brazil’s public health system for WM. Even with those limitations, our results seem to be comparable with previous reported data of the DRC protocol, albeit with lower ORR. Our patients were younger, with lower hemoglobin levels and with more B symptoms than other studies. In addition, difficult access to health care assistance delays diagnosis. Efforts should be made to perform genotype tests and make available specific treatment for MW. Medical education, establishment of a reference center and a national registry may improve knowledge of MW and outcomes of patients in Brazil and other countries.

Keywords: Indolent non-Hodgkin lymphoma, Multiple Myeloma

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