subtypes (3/9–33.3% and 7/16-43.7%, respectively; p = 0.07). So, the mutation *RHOA* was predominantly found in THf cell-derived neoplasms in our cohort. The mutational status of *DNMT3A*, *RHOA* and *TET2* genes had no prognostic impact on OS, with p = 0.85, p = 0.13 and p = 0.95, respectively. The same was observed in relation to PFS for the *DNMT3A* (p = 0.70) and *TET2* (p = 0.52) mutations. However, the presence of the *RHOA* mutation was associated with the unfavorable PFS in our cohort (HR:1.98, p = 0.05). We observed 2-year PFS of 28.6% (95% CI: 8.8-52.4%) for mutated-*RHOA* cases versus 52.9% (95% CI: 37.3-66.3%) for wild-type-*RHOA* patients (p = 0.05). We also demonstrated that the presence of the *RHOA* mutation was a predictor of lower ORR to first-line therapy (p = 0.01) and was associated with high tumor burden (p = 0.03). **Conclusion:** For the first time we demonstrated the unfavorable prognostic impact of the *RHOA* mutation in patients with nPTCL with THf-phenotype, making it a potential molecular biomarker predictor of poor-PFS, associated with resistance to primary therapy and with high tumor burden.

https://doi.org/10.1016/j.htct.2021.10.172

RITUXIMAB BIOSIMILAR RTXM83 POST-MARKETING SURVEILLANCE IN BRAZIL: EVALUATION OF THE ADVERSE EVENTS SPONTANEOUSLY REPORTED TO PHARMACOVIGILANCE

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Background: Biosimilars are highly similar to their reference products, but unlike generic drugs, they are not identical. Differences between a biosimilar and its reference product may arise because of the complexity of biologics, differences in the cell lines and processes used during manufacturing. Biosimilars are approved in Europe, United States and Brazil through a regulatory pathway based on comparative analytical, clinical studies and demonstration of no clinically meaningful differences from their reference products. Post marketing pharmacovigilance is a useful tool to confirm the safety profile of biosimilar medication in the general population, outside of controlled environment of clinical studies. In 2019, rituximab biosimilar RTXM83 was approved in Brazil. **Objective:** The purpose of this communication is to present rituximab biosimilar RTXM83 information collected from adverse events (AEs) spontaneous reports during post-marketing pharmacovigilance activities in Brazil. **Method:** Descriptive retrospective study. Treatment related data and AEs from all spontaneous reports with biosimilar rituximab RTXM83 were reviewed. AEs were classified according to medical terminology (MedDRA) and seriousness assessed by the CTCAE (Common Toxicity Criteria) version 5.0 scale. Descriptive analysis of demographic data and AEs reported was performed. **Results:** A total of 32 reports containing 59 adverse events (AEs) were received from spontaneous reports between September 2019 and July 2021. From 32 reports, 19 were female, 12 were male and 1 not informed. The patients mean age was 48,8 (13 to 81years). The treatment indication was hematology oncology diseases in 23 (72%) patients, autoimmune disease in 7 patients (22%) and not informed in 2 (6%) patients. Regarding AEs seriousness and expectedness, 26 (44%) were non-serious AEs (24 expected / 2 unexpected) and 33 (56%) were serious AEs (22 expected / 11 unexpected). The five most frequently reported AEs according to SOC (System Organ Classification) were immune system disorders 19 (32%), blood and lymphatic system disorders 14 (24%), nervous system disorders 4 (7%), investigations 3 (5%), respiratory, thoracic and mediastinal disorders 3 (5%). The five most commonly reported adverse events (MedDRA PT - Preferred term) were infusion related reaction 18 (31%), neutropenia 6 (10%), anaemia 3 (5%), leukopenia 2 (3%), thrombocytopenia 2 (3%). **Conclusion:** AEs spontaneously reported in patients treated with biosimilar rituximab RTXM83 were consistent with the reference safety information based on literature data and the Summary of Product Characteristics (SmPC) of the reference product. No new safety signals were detected.

https://doi.org/10.1016/j.htct.2021.10.173

SARCOMATOID DIFFUSE LARGE B-CELL LYMPHOMA: A RARE MORPHOLOGICAL VARIANT WITH MULTI-VISCERAL INVOLVEMENT

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Introduction: Diffuse Large B-Cell Lymphoma (DLBCL) is the most frequent subtype of non-Hodgkin's lymphoma (NHL), accounting for 50% of all NHL cases seen at HC-FMUSP. Up to 40-50% of DLBCL cases have extranodal involvement. However, female genital tract involvement is very rare, accounting for less than 0.5% of cases. Spindle/sarcomatoid cell neoplasms usually have mesenchymal histogenesis, however rare cases of aggressive NHL with a spindle-shaped morphological aspect have been recently described, although this variant is still not fully recognized as a specific pathological entity. **Objectives:** To describe a rare case of DLBCL with primary uterine cervix involvement, and sarcomatoid morphological pattern, as well as multi-visceral involvement. We intend to highlight the importance of recognizing this entity in the differential diagnosis of spindle-shaped malignant neoplasms. **Case report:** A 51-year-old woman, with no previous comorbidities, sought medical service at the HC-FMUSP due to a vulvovaginal tumor with progressive growth over the last 12 months. Gynecological examination showed an ulcerated tumor in the cervix, extending to the vaginal cavity and exteriorizing through the vulvar introitus. Computed tomography showed a 7 cm tumor mass in the cervix and pathological bone fracture of the L3 vertebra. A biopsy of the uterine cervix showed atypical fusiform cell proliferation, inferring a diagnosis of uterine leiomyosarcoma. However, bone biopsy showed proliferation of large atypical lymphoid cells,

suggestive of NHL. Immunohistochemical study of both samples revealed: Ki67+ (80%), CD45+, PAX-5+, diffuse staining for CD20+, BCL-6+, CD79a+, CD30+, with negativity for epithelial and mesenchymal lineage markers. 18-FDG-PETCT revealed involvement of lymph nodes, bones, liver, kidney, thyroid, breasts and bulky in the female genital tract. Diagnosis of DLBCL sarcomatoid variant was established and therapy was scheduled with 6 x R-CHOP, 3 cycles of 3 g/m^2 methotrexate for CNS prophylaxis and uterine cervix radiotherapy depending on residual uptake on PET-CT after chemotherapy. She is currently after 1st. R-CHOP cycle. **Discussion:** Sarcomatoid variant of DLBCL is rare and already recognized as a morphological variant of DLBCL NOS by WHO-2016 Classification. The explanation for the occurrence of fusiform neoplastic cells remains unclear, but it is believed that tumor stromal fibrosis can justify deformation of the cell membrane of neoplastic cells, giving the sarcomatoid aspect. Its clinical significance, as well as prognostic impact, have not been established, nor has there been any definition of the need for therapy different from conventional treatment based on anthracyclines (R-CHOP). **Conclusion:** We described a case of uterine cervix sarcomatoid DLBCL, a rare entity that establishes a differential diagnosis with sarcomas of the female genital tract. Although it is an isolated case, our patient had multivisceral involvement and high-risk IPI, leading us to infer that this morphological variant may be related to greater biological aggressiveness, high tumor burden and poor outcomes, but this needs to be validated with description of other cases and cases series.

https://doi.org/10.1016/j.htct.2021.10.174

SARS-COV-2 INDUCED REMISSION OF DIFFUSE LARGE B-CELL LYMPHOMA: A CASE REPORT

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Introduction: Diffuse Large B-cell lymphoma (DLBCL) is the most common non-Hodgkin lymphoma, which accounts for approximately 30% of all non-Hodgkin lymphoma cases. Spontaneous remission of DLBCL is exceedingly rare, with only a handful of case reports that describe the phenomenon present in the literature. Specialists are investigating similar cases to find out whether the SARS-CoV-2 infection triggered an antitumor immune response, as has been described with other infections in the context of high-grade non-Hodgkin lymphoma. We report one case of an elderly woman with EBV positive DLBCL diagnosed with PCR-positive SARS-CoV-2 pneumonia in the course of the disease and their outcomes. Case report: A 81 years-old woman, was referred to the consult ambulatory of intern medicine with progressive cervical, axillary and inguinal lymphadenopathy with local pain, fever and weight loss. The biopsy of an axillary lymph node demonstrated diffuse atypical lymphoid infiltrate. Immunohistochemistry stains showed positive CD20, CD30, Bcl-2 and MUM-1. It was negative for CD3, CD10, Bcl-6, c-Myc and CMV. The Ki-67 proliferation index was 80%. Epstein-Barr virus (EBV) stain were positive. These findings were consistent with DLBCL, EBV positive, clinical Stage IIIB and R-IPI 4 (poor prognosis and high risk). Since PET-CT was unavailable, thorax and abdomen computed tomographies were performed and revealed enlarged lymph node on pulmonary hilum, pathological lymph node enlargement in the axillary and supraclavicular chains bilaterally and peri aortocaval adenomegaly, extending along the bilateral femoral iliac vessels (larger lymph nodes of 2.5cm). She was treated with 4 cycles of R-CVP (rituximab with cyclophosphamide, vincristine and prednisone). When an interim PET-CT was performed, disease progression was revealed (Lugano score 5). Therefore, considering patient age and clinical status, treatment scheme was changed to R-mini-CHOP (rituximab with reduced doses of cyclophosphamide, doxorubicin, vincristine and prednisone), achieving partial response after 4 cycles (Lugano score 4). A month after this evaluation, she was admitted to the Emergency Department with diarrhea, fever and was diagnosed with PCR-positive SARS-CoV-2 pneumonia. After 6-days hospitalization with no significant ventilatory impairment, she was discharged. No corticosteroid or immunochemotherapy was administered. Two months later, she had no palpable lymphadenopathy and a PET/CT scan revealed widespread resolution of the lymphadenopathy and reduced metabolic uptake throughout (Lugano score 1). After a 7-months follow-up, the patient still has no clinical relapse. **Discussion:** The putative mechanisms of action include cross-reactivity of pathogen-specic T cells with tumour antigens and natural killer cell activation by inammatory cytokines produced in response to infection. It is important to consider that the more cases of SARS-CoV-2 infection in patients with non-Hodgkin lymphoma, the more likely it is to analyze lymphoma remissions and demonstrate the exact mechanism of pathogen-specific T cells with tumor antigens. **Conclusion:** Because spontaneous remission of DLBCL associated with SARS-CoV-2 infection is a new event, careful investigation of these cases is important, because the information gained may lead to new therapeutic targets or treatment strategies for future patients.

https://doi.org/10.1016/j.htct.2021.10.175

SCIMITAR SYNDROME IN A PATIENT WITH NON-HODGKIN'S LYMPHOMA: A RARE CASE REPORT IN THE BRAZILIAN AMAZON

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