Cytopenia (1) and Bullous Dermatitis (1). One report included more than 1 manifestation.

Additionally, we detected the occurrence of off-label use(*) in 6.6% treatments.

Conclusion: The activities developed under this active pharmacovigilance program are showing great value allowing us to continuously monitor the safety profile of this biosimilar product. In this report the biosimilar product NOVEX® showed a safety profile similar to what has been described with the reference product. Therefore, in terms of tolerability, the biosimilar product has a comparable profile with the reference product.

Keywords: monoclonal antibodies (MoAb); non-Hodgkin lymphoma (NHL); rituximab.

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REAL-LIFE USE OF BENDAMUSTINE FOR B-CELL NON-HODGKIN LYMPHOMA IN A COMMUNITY HOSPITAL IN JAPAN—RETREATMENT WITH BENDAMUSTINE IS SAFE AND FEASIBLE

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Introduction: Bendamustine is an alkylating agent with antimetabolite properties that has little cross resistance to other alkylating agents and purine analogues. It has shown to be effective in treatment of relapsed/refractory (R/R) chronic lymphocytic leukemia (CLL) and indolent B-cell non-Hodgkin lymphomas (NHL). Combination of bendamustine with rituximab is currently actively incorporated not only in R/R settings but also in first line treatment of these diseases. Once patients relapse after bendamustine (B)-containing therapy, data is limited on whether retreatment with bendamustine is feasible. In this study, we assessed the utility of B-containing regimen in a community hospital in Japan, especially focusing on the feasibility of retreatment with bendamustine.

Methods: Patients with B-NHL treated with B-containing therapy were identified from our pharmacy database. Relevant clinical information was retrospectively collected from the patients' medical record.

Results: We identified 39 patients with B-NHL treated with B-containing therapy. The median age of the patients was 70 years old (range 39–88). The male to female ratio of the patients was 25:14. Twenty-nine patients were initially diagnosed as indolent B-NHL (follicular lymphoma (FL): 23, mantle cell lymphoma (MCL): 4, small lymphocytic lymphoma (SLL): 1, splenic marginal zone lymphoma (SMZL): 1), and the remaining 10 had diffuse large B-cell lymphoma (DLBCL). The median number of treatment prior to bendamustine use was 1 (range 1–17). Patients were treated with a median of 3 (range 1–66) cycles of B-containing regimen, and the overall response rate (ORR) was 59.0% (CR: 10, PR: 13, SD: 6, PD: 10). The median overall survival and progression-free survival was 60 (0.5-68.8+) months and 10 (0.3–68.6+) months, respectively.Among these patients, 10 were retreated with B-containing therapy at subsequent relapses. The median time from initial treatment was 14.8 (range 9.1–38.0) months. Seven patients had FL, 2 had DLBCL and 1 had MCL. The ORR of second bendamustine treatment was 100% (CR: 3, PR: 7). Among the 8 patients who subsequently relapsed or had progression of disease, 4 patients were further treated with B-containing regimen, and the median number of bendamustine treatment beyond first progression among all 10 patients was 5 (range 1–13) cycles. There was no apparent increase of infection after retreatment with bendamustine.

Table 1: Distribution per indication of patients included in the analysis

Indication	#	%
Folicular non-Hodgkin lymphoma	195	51.6%
Diffuse large B-cell non-Hodgkin's lymphoma	114	30.2%
Chronic lymphocytic leukemia	44	11.6%
Other non-Hodgkin lymphomas*	25	6.6%

Conclusions: Treatment of R/R B-NHL with B-containing therapy in a single institute yielded similar results to previous reports. Retreatment with B-containing regimen showed high response rate with few complications, making multiple retreatment possible in some patients. Bendamustine retreatment should be considered a treatment option in patients relapsed beyond first treatment with bendamustine.

Keywords: B-cell lymphoma; bendamustine.

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THALIDOMIDE IN RELAPSED LYMPHOMA: 5 YEARS OF EXPERIENCE FROM SOUTHEND UNIVERSITY HOSPITAL NHS FOUNDATION TRUST

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Introduction: Thalidomide is an immunomodulatory and anti-inflammatory drug with well-documented efficacy in the treatment of multiple myeloma, both as initial therapy and in relapsed disease. Known side effects include venous thrombosis, fatigue, peripheral neuropathy and constipation. However as an oral drug with minimal myelosuppression, thalidomide is suitable for patients unable to tolerate more conventional chemotherapy or for whom regular hospital attendances are too demanding.Data from clinical trials and case series in a range of both B- and T-lymphoproliferative disorders show broad efficacy of thalidomide. The unusual and multiple modes of action of thalidomide suggest potential in treating disease resistant or refractory to conventional chemotherapy. This is further supported by exceptional case studies such as a refractory AITL patient achieving CR with thalidomide/dexamethasone and a post-allograft DLBCL patient achieving CR on thalidomide/rituximab.We have been using Thalidomide in relapsed and frail lymphoma patients at Southend for a number of years with anecdotally good outcomes. We decided to conduct a retrospective study of lymphoma patients treated with thalidomide

to assess the rates of response and overall survival, as well as examining the side effect profile.

Methods: Data from 2012 to 2016 were collected retrospectively from pharmacy records for all lymphoma patients treated with thalidomide. The majority of these patients were multiply relapsed. Patients were all started on 50 mg daily, with dose escalation to 200 mg daily as tolerated, in addition to pulsed dexamethasone.

Results: 27 patients were treated: - 11 DLBCL (2 transformed low-grade) - 3 Follicular lymphoma- 2 B-NHL unspecified- 3 Hodgkin's disease- 2 Waldenström's macroglobulinaemia- 1 mantle cell- 5 angioimmunoblastic T cell- Age range of patients 52–58 (median age 75)- Line of treatment was 1–5 (median 2)- 17/27 patients were treated for >4 weeks (others stopped due to SEs or early relapse/death)- 7 of those 17 achieved disease control for >6 months.

Conclusion: The patients examined in this study were all multiply relapsed and/or too frail for conventional chemotherapy. Prognosis in such a cohort is very poor and, unsurprisingly, many of the cases we looked at died shortly after starting treatment. However, a subset of these patients achieved long disease control—one patient is still alive 5 years after starting thalidomide. Thalidomide has a variety of mechanisms including immunomodulatory and anti-angiogenic properties so it is a logical choice of treatment in chemotherapy-resistant cases. Given the generally well-tolerated side effect profile and low cost of thalidomide not to mention the ease of administration, a trial of thalidomide is worth considering when no other options remain, where it may buy precious months, or even years, of life.

Keywords: B-cell lymphoma; immunomodulators (IMIDs); T-cell lymphoma (TCL).

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COMPARATIVE ANALYSIS OF PREDICTIVE MODELS FOR THROMBOEMBOLIC EVENTS IN LYMPHOMA PATIENTS

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Introduction: Actual guidelines recommend Padua and Khorana score for thromboembolic (TE) risk estimation for cancer patients in general. These existing models are quite limited for designation of lymphoma patients for TE events, as their development is not based on features specific for hematological patients. The aim of this study was to compare diagnostic performance of these suggested predictive models, as well as Thrombosis lymphoma (Throly) score, developed by our group, which is more specific for lymphoma patients.

Methods: The study population included all consecutive patients with a histological confirmed diagnosis of non-Hodgkin lymphoma (NHL), Hodgkin lymphoma (HL), and chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), who were treated in the Lymphoma Departments of Clinical Center Serbia and Clinical Center Kragujevac. From January 2006 to December 2014, data were prospectively collected and entered into the institutional Lymphoma database. The study population was divided based on a split-sample random method into the model developing and validation cohorts. The ThroLy model was developed using data solely from a derivation cohort, which included 1236 patients. Variables were evaluated by univariate logistic regression analysis, while the model was developed using a stepwise multivariate logistic regression analysis. Once a final model was defined, patients were divided into *low risk* and *at risk* groups. The final model was assessed in the validation cohort (584 patients). The studied population was also divided, based on Khorana and Padua score, into *low risk* and *at risk* groups.

Results: The incidence of thromboembolism was 81 (5.3%) in the newly diagnosed patients and 18 (6.2%) in relapsed patients. Overall, 35.4% (35/99) of the patients with thromboembolism experienced the event before the start of chemotherapy. The majority of patients (64.6%) had TE events during chemotherapy or within 3 months after chemotherapy. Cohorts were balanced regarding the incidence of events (5.3% and 5.5% in derivation and validation cohort, respectively). For patients classified *at risk* according to ThroLy score in derivation cohort, the model produced negative predictive value (NPV) of 98.5%, positive predictive value (PPV) of 25.1%, sensitivity of 75.4%, and specificity of 87.5%. In validation cohort PPV for Throly score was 28.9%. Padua and Khorana score had PPV of 15.5% and 14.8% in derivation, and 11.5% and 14.8% in validation cohort, respectively.

Conclusion: Lymphoma patients are at increased risk of thromboembolic events but thromboprophylaxis in these patients is largely underused. ThroLy score is more specific for lymphoma patients than suggested Padua and Khorana score, but external validation in large prospective cohort studies is required.

Keywords: Hodgkin lymphoma (HL); non-Hodgkin lymphoma (NHL).

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INCIDENCE AND SURVIVAL OF NON-HODGKIN LYMPHOMA AT ONCOSALUD—AUNA: A DYNAMIC COHORT STUDY

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Background: Non-Hodgkin lymphoma (NHL) is the most common malignancy in many countries and regions; it represents the twelfth cause of death in the world and the eleventh cause of death in the Peruvian population. The incidence of lung cancer in a population affiliated with a prepaid system is important for the implementation of prevention programs. The arm of study was to determinate the incidence rate of NHL in a population of affiliates and the survival rate of patients treated in a private institution (ONCOSALUD—AUNA).

Methods: In a study of dynamic cohort, the incidence of LNH was evaluated in a population of affiliates to ONCOSALUD—AUNA