10.2478/prilozi-2026-0010 ISSN 1857-9345

RESPONSE RATE IN CLL PATIENTS TREATED WITH OBINUTUZUMAB - SINGLE CENTRE EXPERIENCE FROM UNIVERSITY CLINIC OF HEMATOLOGY, SKOPJE

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ABSTRACT

The glycoengineered humanized monoclonal type II anti-CD20 antibody obinutuzumab is widely used in the treatment of patients with chronic lymphocytic leukemia (CLL), most commonly in combination with other therapeutic agents.

The aim of this single-centre retrospective study was to evaluate the treatment patterns and clinical responses in patients with CLL treated with obinutuzumab-based combination regimens at the University Clinic of Hematology, Skopje.

We analyzed 90 patients with CLL treated with obinutuzumab-based regimens between 2019 and 2024. Obinutuzumab was administered in combination with chlorambucil (56.6%), fludarabine–cyclophosphamide (26.6%), bendamustine (11.1%), CVP (4.4%), or venetoclax (5.5%). The treatment was given as first-line therapy in 57.7% of patients and in the relapsed/refractory setting in 42.3%.

The median age at initiation of obinutuzumab-based therapy was 66.9 years. The overall response rate to obinutuzumab-based treatment was 45.5%. The median follow-up after treatment was 15.6 months.

In this real-world single-centre experience, obinutuzumab-based combination regimens showed measurable clinical activity in routine practice across different treatment lines. Longer follow-up and larger patient cohorts are required to better characterize the durability of the responses and outcomes in the specific treatment subgroups.

Keywords: chronic lymphocytic leukemia, obinutuzumab, combination therapy

INTRODUCTION

Chronic lymphocytic leukemia (CLL) is the most common type of leukemia in adults in Western Europe and North America and represents about 30% of all leukemia's in adults. CLL is a disease of elderly, most patients with CLL are older than 70 years of age and have clinically relevant coexisting conditions. These factors affect further treatment decisions, despite the great progress in the therapy of CLL in the last two decades [1].

Some patients with CLL have an indolent disease that does not require therapy for many years and therefore those patients are followed up using the *watch and wait* strategy. Conversely, other patients have an aggressive disease that

requires treatment soon after diagnosis and/or may subsequently undergo histologic transformation into an aggressive lymphoma, known as Richter syndrome (RS) [2]. There are several prognostic factors that could predict an unfavourable course of the disease. The most relevant and powerful are the somatic mutations of immunoglobulin heavy chain variable (IGHV) genes, chromosomal alterations like deletions of chromosomes 13q, 17p, 11q, trisomy 12, and recurrent gene mutations of several genes including *TP53*, *ATM*, *SF3B1*, *BIRC3* and *NOTCH1* genes [3,4]. CLL has a classic immunophenotype, consisting of light chain restriction, CD5+, CD19+, dim CD20, CD23+, CD43+, CD200+, CD10- and CD79b-. This distinguishes it from normal B cells and other lymphoproliferative disorders (LPDs) [5].

There are two types of CD20 monoclonal antibodies. Type I antibodies such as rituximab and ofatumumab bind to CD20 and induce a quick redistribution of the antibody–antigen complex into a lipid raft, which leads to strong complement-dependent cytotoxicity (CDC) by recruiting C1q. In contrast, type II antibodies such as obinutuzumab obtain reduced FcγRIIb-mediated CD20 internalization that increases the capacity to bind and activate natural killer (NK) cells and the subsequent immune effector functions [6].

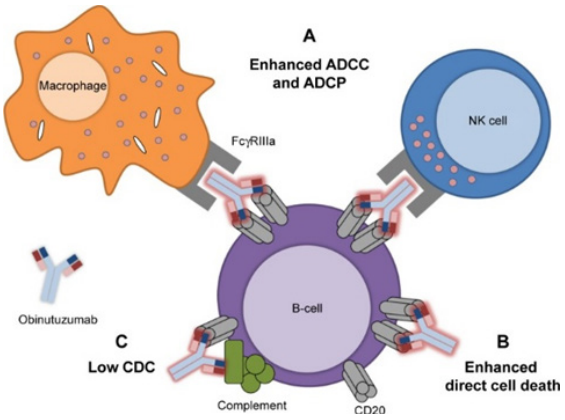


Figure 1. *Mechanism of action of obinutuzumab: Modification of the glycan tree structure at the Fc fragment of obinutuzumab leads to an increased affinity to FcγRIII and thereby ADCC via NK cells as well as ADCP via macrophages is intensified [6]*

The monoclonal anti-CD20 antibody rituximab, combined with chemotherapeutic agents, has been shown to prolong overall survival in physically fit patients with previously untreated CLL but not in those with coexisting conditions [7]. One approach to achieving more durable responses was the development of Obinutuzumab (GA101), a new type of CD20 antibody that has unique molecular and functional characteristics. Obinutuzumab is a type II fully humanized CD20 antibody that binds to a partly different epitope of the CD20 protein than rituximab and due to its glycoengineered design induces greater antibody-dependent cell-mediated cytotoxicity (ADCC) [6]. The efficacy of Obinutuzumab has been shown during the many trials conducted since its emergence, as in the Phase I/II GAUGIN trial, the following GAGE trial, the GALTON trial, the pivotal CLL11 trial by the German CLL Study Group (GCLLSG), and the GOYA trial. All the trials tested the medication combined with other treatments previously used and/or compared its efficacy on a long-term basis. Taken together, the cumulative benefit of Obinutuzumab has been shown to be superior to Rituximab. Moreover, the GREEN trial [7], which represents a phase IIIb, multicentre, open label trial, explored the safety and efficacy of Obinutuzumab alone or in combination with chemotherapy (bendamustine, chlorambucil or cyclophosphamide/fludarabine). Finally, the CLL14 trial as a successor trial to CLL11, testes the combination of Obinutuzumab with bcl-2 inhibitor Venetoclax, which all-together makes the horizon of therapeutic strategies in CLL wider. In recent years, the therapeutic landscape of CLL has expanded substantially with the introduction of targeted agents. Obinutuzumab has been approved by the European Medicines Agency for use in combination with venetoclax, ibrutinib, and acalabrutinib-based regimens, and these combinations are currently among the most widely recommended options for first-line treatment of CLL.

The most common adverse effects of Obinutuzumab noted are infusion related reactions (IRRs), neutropenia and thrombocytopenia, particularly during the first administration. This is due to the high cytokine release during the first administration, as concluded in a study on 38 patients with CLL, which were starting treatment with Obinutuzumab [8].

The worldwide approval of the novel antibody in the indication field of CLL was based on the primary results of the CLL11 study (NCT010110061), which compared Obinutuzumab (also known as GA101) plus chlorambucil (G-Clb) with rituximab plus chlorambucil (R-Clb) and chlorambucil alone (Clb) in patients with previously untreated CLL and comorbidities [6].

In North Macedonia, initially, Obinutuzumab (Gazyva) was approved for the first-line treatment of patients with CLL (1L CLL) in October 2015. The introduction of obinutuzumab expanded the available therapeutic options for patients with CLL, particularly in combination-based regimens. This approval was followed by the Macedonian Agency for Medicines and Medical Equipment (MALMED) approval of Obinutuzumab plus bendamustine regimen in Relapsed/Refractory (R/R) Follicular lymphoma in April 2017. Afterwards, the journey of approval culminated with the Obinutuzumab-chemotherapy approved regimen in May 2018. Ever since the first permission for usage, the first application of Gazyva at the University Clinic for Haematology was in 2016, when 2 patients with CLL were treated with first-line therapy with Gazyva - Bendamustine and Gazyva-FC accordingly.

There are several precautions preceding the administration of Gazyva for the first time. The protocol obligates the coordinating haematologist to evaluate the patient prior Gazyva infusion for tumor lysis syndrome (TLS) risk and hepatitis B reactivation. Accordingly, aall patients should be tested for hepatitis B surface antigen (HBsAg), hepatitis B core antibody (anti-HBc) and HCV. If serology is positive, consultation with an experienced physician in the management of hepatitis B is warranted to evaluate for appropriate prophylaxis and monitoring prior to initiating therapy with Gazyva.

Patients with tumors with large tumor mass and/or high circulating lymphocyte counts (> 25 x 109/L) and/or renal insufficiency (creatinine clearance <70 ml/min) are at risk of developing TLS and should receive prophylaxis. Prophylaxis should consist of adequate hydration and administration of allopurinol, or appropriate alternative treatment, such as urate oxidase (e.g. rasburicase), starting 12 to 24 hours before the start of the Gazyva infusion according to the standard clinical practice. Patients should continue to receive prophylaxis before each subsequent infusion if it is deemed or appropriate. Hypotension, as a symptom of an infusion-related reaction, may occur during the administration of Gazyva by intravenous infusion. Therefore, physicians should consider discontinuing the use of antihypertensive therapy 12 hours before and during each Gazyva infusion and during the first hour after intravenous administration.

An appropriate premedication should be considered before every administration of Gazyva. Premedication that is used currently in North Macedonia is the one from the GREEN study: Dexamethasone 20 mg orally 12 hours prior treatment, Methylprednisolone 80 mg one hour, Paracetamol 1000 mg and Chloropyramine 30 minutes before infusion.

The objective of this study was to describe treatment patterns and evaluate clinical responses in patients with CLL treated with obinutuzumab-based combination regimens at a single tertiary referral centre, in both first line and relapsed/refractory settings.

MATERIALS AND METHODS

We have analyzed medical records of 90 patients with CLL that have been treated with Obinutuzumab (Gazyva) based protocols in our institution in the period between 2019 and 2024. All patients were diagnosed at the University Clinic for Hematology in Skopje, with standard diagnostic procedures according to the recommendation of IWCLL (International Workshop on Chronic Lymphocytic Leukemia) and staged with Rai staging system. Patients with Rai stage 0–I disease were treated due to the presence of active disease according to IWCLL criteria, including progressive lymphocytosis, symptomatic lymphadenopathy or splenomegaly, cytopenias, or disease-related symptoms. Most used protocols in our study were Obinutuzumab-Chlorambucil (56,6%) and Obinutuzumab-FC (Fludarabine+-Cyclophosphamide) protocol (26.6%).

The medical records of these patients were reviewed retrospectively for the clinical and laboratory information regarding their diagnosis, demographics, CLL stage and disease duration, initial treatment, time to first treatment, previous treatment lines, response rate to Obinutuzumab based treatment, duration of response after treatment, death rates, cause of deaths and molecular prognostic factors present during the disease evolution. Baseline complete blood count values were included to describe disease burden and hematologic status at diagnosis and to provide context for treatment initiation and subsequent response assessment.

All collected data were analyzed using standard statistical tests in Microsoft Office Excel 2023.

RESULTS

According to the data collected from the system of University Clinic of Haematology, every year since 2019, more than 50 patients per year have been diagnosed with CLL in North Macedonia (Figure 2.), except in 2020 due to Covid closing quarantines and patients avoiding health institutions given the rules for prevention of SarsCOV2, and during the year of 2024. Around third of the annual newly diagnosed CLL patients have been given Gazyva.

Most of the patients diagnosed with CLL in this study were in their 8th decade (Figure 3.). The median age of our group of patients at the time of diagnosis of CLL was 62.1 years (range: 35-79 years), while median age at the start of Gazyva treatment was higher 66.9 years (range: 35-86). Seventy-one patients 71/90 (79%) were males and 19/90 (21%) were females. Regarding the age distribution at the time of diagnosis, twenty patients 20/90 (22%) were under the age of 60 years, 30/90 (33%) were between 60-70 years, 35/90 (39%) were between 70-80 years and 5 patients were older than 80 years. We have used the Rai prognostic model. Most of the observed patients were Rai Stage 1 (43.2%), 9.5% were Rai Stage 2, 16.3% were Rai Stage 3 and 6.7% were Rai Stage 4.

The median follow up from the diagnosis of CLL was 61.8 month (Range: 3-288 months), while the median follow up after the Gazyva treatment was 15.6 months (Range:6-62 months). The calculated median time to first treatment (TTFT) in months was 23.8 (Range:0-120 months). The median time to first treatment with Gazyva (TTFTG) was 43.2 months (Range:0-160 months) (Table 1).

The median complete blood count (CBC) results at the time of diagnosis were: Hgb 125 g/L (range 53-170 g/L), WBC 97.4 × 10^9/L (range 11.4-663 × 10^9/L), PLT 182 × 10^9/L (range 9-439 × 10^9/L). At the time of the last control the average hemoglobin level was 127g/L (80-178g/L), the average white blood cell count was 23.2 (0.1-300x10^9/L) and the average platelet count was 155(12-398x10^9/L) (Table 1).

As for remission/response rate calculated in this single-center retrospective analysis which further needs validation among other cohorts of patients, remission/response was noted in the 41 of the total number of 90 patients treated with obinituzumab (45.5% of the patients responded to treatment) (Table 1).

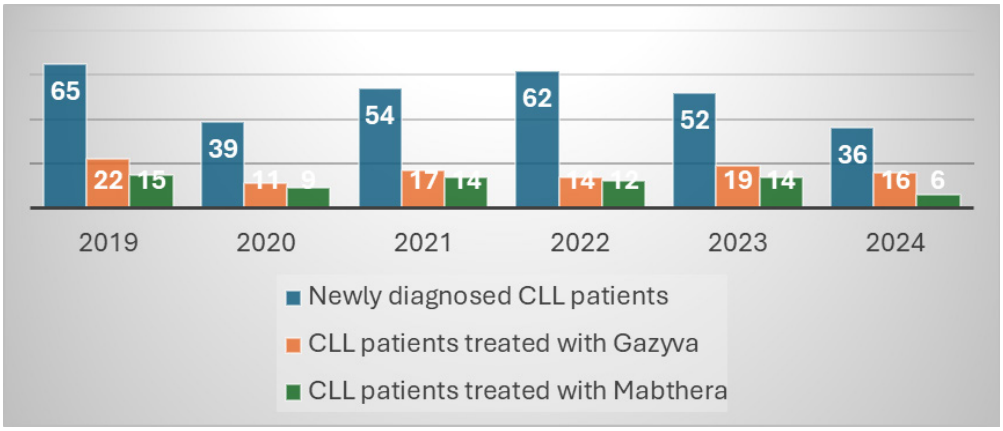
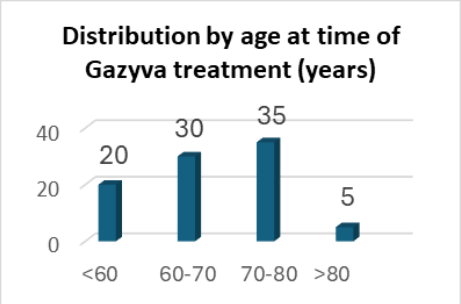


Figure 2. *Data from the University Clinic of Haematology (January 2019-November 2024)*



Rai "0"	24.3%
Rai "1"	43.2%
Rai "2"	9.5%
Rai "3"	16.3%
Rai "4"	6.7%

Figure 3.

The median number of Gazyva doses per patient was 5.2 (Range:1-8). Gazyva was used as first line treatment in 52/90 (57.7%), as second line treatment in 26/90 (28.8%), as 3rd line treatment in 12 out of 90 (13.3%),4th line treatment in 6/90 (6.6%) and multiple line of treatment 6/90 (6.6%). The most used Gazyva based regiment in this study was G-Chlorambucil in 51/90 (56.6%), 24/90 (26.6%) were treated with G-FC, 4/90 (4.4%) of patients were treated with G-CVP, 10/90 (11.1%) with G-Bendamustine and 5/90 (5.5%) with G-Venetoclax (Table 2).

Gazyva based protocols were used as 1st line treatment in 52/90 patients (57.7%), as 2nd line treatment in 26 out of 47 patients (55.3%), as 3rd line treatment in 12/22 patients and 6 out of 10 patients were treated with Gazyva based protocols in 4th line setting (Table 3).

The total number of deaths registered in this study was 33/90 (36.6%), 75.7% of all deaths were CLL related with infections as the most common cause of deaths in 19 out of 25 patients (76%). COVID was a cause of death in 6 out of 33 patients. CLL nonrelated deaths were noticed in 8 out of 33 patients (24.3%) (Table 4). Richter transformation was confirmed in 3 out of 90 patients (3.3%). In our group of patients, we had molecular prognostic markers for only 34 patients and mutations in TP53 were present in 7 out of 24 patients (29%) (Table 4).

Table 1. *Median follow up CLL patients, CBC results and response rate to Gazyva treatment*

	Total: 90 patients
Median follow up from diagnosis - months	61.8 months (Range: 3-288)
Median follow up after Gazyva based therapy - months	15.6 months (Range: 0-62)
TTFT (time to first treatment) - months	23.8 months (Range: 0-120)
TTFGT (time to first Gazyva treatment) - months	43.2 months (Range: 0-160)
CBC at diagnosis	Hgb 125 (53-170) WBC 97.4 (11.4-663) Plt 182 (9-439)
CBC at last control	Hgb 127 (80-178) WBC 23.2 (0.1-300) Plt 155 (12-398)
Remission/Response	41/90 (45.5%)

Table 2. *Distribution by treatment type*

	Total: 90 patients
Median number of Gazyva doses per patients	5.2 (Range:1-8)
Distribution by treatment line	1st Line 52/90 (57.7%) 2nd Line 26/90 (28.8%) 3rd Line 12/90 (13.3%) 4th Line 6/90 (6.6%) *Multiple Lines 6/90 (6.6%)*
Distribution by treatment type	G-Chlorambucil 51/90 (56.6%) G-FC 24/90 (26.6%) G-CVP 4/90 (4.4%) G-Bendamustine 10/90 (11.1%) G-Venetoclax 5/90 (5.5%)

Table 3. *Distribution by treatment type*

	1st Line	**2nd Line**	**3rd Line**	**4th Line**
FCR	24	5	2	/
FC	3	3	2	/
Chlorambucil	3	6	2	2
R-Chlorambucil	3	3	1	/
G-Chlorambucil	33	8	7	3
G-FC	17	4	2	1
G-Venetoclax	1	4	0	1
G-Bendamustine	1	8	1	/
Fludarabine, G-CVP, Ibrutinib, Others	5	6	5	3
Total	**90**	**47**	**22**	**10**
Gazyva based therapy	52/90 (57.7%)	26/47 (55.3%)	12/22 (54.5%)	6/10 (60%)

Table 4. Death rate and causes of deaths.

	Total: 90 patients
Total number of deaths	33/90 (36.6%)
CLL related deaths, due to the nature of the disease	Total 25/33 (75.7%) Infections 19/25 (76%) COVID 6/25 (24%)
CLL non related deaths (CVI, Diabetes complication, hip fracture)	8/33 (24.3%)
Richter transformation	3/90 (3.3%)

DISCUSSION

This single-centre retrospective analysis describes real-world use of obinutuzumab-based combination regimens in a heterogeneous cohort of patients with CLL treated in both first line and relapsed/refractory settings. In our study, the overall response rate of 45.5% reflects outcomes across multiple treatment combinations, lines of therapy, and patient characteristics, which complicates the direct comparison with prospective clinical trials.

In pivotal randomized trials such as CLL11 and CLL14, obinutuzumab-based combinations demonstrated higher response rates and prolonged progression-free survival compared with chemoimmunotherapy backbones; however, these trials enrolled more homogeneous patient populations and followed predefined treatment protocols. In contrast, our cohort represents routine clinical practice, where treatment selection was influenced by age, comorbidities, prior therapies, and drug availability.

The median age at initiation of obinutuzumab-based therapy in our cohort is comparable to that reported in other real-world studies, including retrospective analyses from European centres. The inclusion of patients treated in later lines likely contributed to the lower observed response rate compared with frontline clinical trial data.

Limitations of this study include its retrospective design, limited molecular characterization, heterogeneous treatment regimens, and relatively short follow-up. Additionally, the lack of a comparator group precludes conclusions regarding the superiority or comparative efficacy of the obinutuzumab-based therapy.

Despite these limitations, our data provide insight into the real-world use of obinutuzumab-based combinations in a national referral centre and support their continued use as part of the combination strategies in CLL. Larger multicentre studies with longer follow-up are needed to better define outcomes in specific treatment subgroups.

CONCLUSION

Obinutuzumab-based combination regimens demonstrated measurable clinical activity in this heterogeneous real-world cohort of patients with CLL. Given the retrospective design, heterogeneous treatment regimens, and absence of a comparator group, no conclusions regarding comparative efficacy can be drawn. Larger prospective studies with longer follow-up are required to better define the depth and durability of responses.

Funding

This report received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Conflict of interest statement

The authors declare there are no conflicts of interest in preparing this article.

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Резиме

СТАПКА НА ОДГОВОР ОД ТЕРАПИЈА КАЈ ПАЦИЕНТИ СО ХЛЛ ТРЕТИРАНИ СО ОБИНУТУЗУМАБ – ИСКУСТВО ОД УНИВЕРЗИТЕТСКАТА КЛИНИКА ЗА ХЕМАТОЛОГИЈА, СКОПЈЕ

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Хуманизираното моноклонално анти-CD20 антитело тип II, обинитузумаб, се користи во третман на пациенти со хронична лимфоцитна леукемија (ХЛЛ). ХЛЛ е најчестиот тип леукемија во Западна Европа и во Северна Америка и претставува околу 30 % од сите дијагностицирани леукемии кај возрасните. ХЛЛ е болест на постарите лица, кои често имаат повеќе коморбидитети, кои влијаат на понатамошните одлуки за третман.

Целта на оваа студија беше да се евалуираат резултатите од третманот со обинутузумаб на пациентите со ХЛЛ во нашата институција.

Анализиравме вкупно 90 пациенти со ХЛЛ, кои биле третирани со третмани базирани на обинутузумаб во период од 6 години, од 2019 до 2024 година.

Просечната возраст на пациентите во време на поставување на дијагноза ХЛЛ беше 62,1 година (опсег: 35–79 години), додека средната возраст при почетокот на третманот со обинутузумаб беше 66,9 години (опсег: 35–86). Седумдесет и еден пациент (79 %) беа мажи. Просечното следење на пациентите брои 61,8 месеци, додека средното следење по третманот со обинутузумаб (Gazyva) е 15,6 месеци. Пресметаното средно време до првиот третман беше 23,8 месеци (опсег: 0–120 месеци). Просечното време до првиот третман со Gazyva беше 43,2 месеци (опсег: 0–160 месеци).

Ремисија/одговор беше забележан кај 45,5 % од пациентите третирани со Gazyva, што претставува одлична стапка на одговор во споредба со другите претходно користени стратегии за третман на оваа состојба.

Резултатите од нашата студија се во согласност со резултатите од другите достапни студии. Резултатите за ефикасноста на обинитузумабот покажуваат зголемена стапка на одговор од третманот, но потребно е дополнително следење на дадените пациенти и/или поголема група испитаници за да се процени длабочината и истрајноста на одговорите од терапијата.

Клучни зборови: хронична лимфоцитна леукемија, обинитузумаб, комбинирана терапија