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CLADRIBINE IN THE TREATMENT OF HAIRY CELL LEUKEMIA – A SINGLE-CENTRE TEN-YEAR EXPERIENCE

PRIMENA KLADRIBINA U LEČENJU TRIHOLEUKEMIJE − DESETOGODIŠNJE ISKUSTVO JEDNOG CENTRA

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Summary

Introduction. Hairy cell leukemia is a rare, indolent chronic lymphoproliferative disorder characterized by circulating B cells with cytoplasmic projections, pancytopenia, and recurrent infections. This study aims to evaluate the efficacy and safety of cladribine in managing the disease among patients treated at the Clinical Centre of Vojvodina. **Material and Methods**. This study included 34 patients with immunohistochemically confirmed hairy cell leukemia, treated with cladribine from September 2013 to December 2023. Clinical data were reviewed and analyzed using standard statistical methods. **Results.** At the time of cladribine administration, the median age was 53; 50% of patients were symptomatic, 65% had pancytopenia, and 62% presented with splenomegaly. After the first cycle, 68.75% of patients achieved a complete hematologic response, and the overall response rate was 100%. The median follow-up period was 51 months. During this period, two patients were diagnosed with non-melanoma skin cancers, one with renal cell carcinoma, and one with both myelodysplastic syndrome and prostate cancer. Additionally, 88% of patients experienced at least one infection, with viral infections being the most frequent complications. Four patients died during the follow-up period, and the 5-year survival rate was 97%. **Conclusion.** Cladribine is an effective treatment for hairy cell leukemia, demonstrating a good safety profile and potential for long-term remission.

Key words: Cladribine; Leukemia, Hairy Cell; Antineoplastic Agents; Treatment Outcome

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Sažetak

Uvod. Leukemija vlasastih ćelija je retka indolentna hronična limfoproliferativna bolest, koja se karakteriše cirkulišućim B-ćelijama sa citoplazmatskim produžecima, pancitopenijom i učestalim infekcijama. Cilj ovog istraživanja je da se ispita efikasnost i bezbednost kladribina u tretmanu ove bolesti među bolesnicima koji su lečeni u Kliničkom centru Vojvodine. **Materijal i metode.** U studiju su uključena trideset i četiri bolesnika sa imunohistohemijski potvrđenom dijagnozom leukemije vlasastih ćelija koji su lečeni kladribinom od septembra 2013. do decembra 2024. godine. Podaci su obrađeni standardnim statističkim metodama. **Rezultati.** U vreme primene kladribina medijana starosti je bila 53 godine; 50% bolesnika je imalo simptome bolesti, 65% pancitopeniju, a splenomegalija je bila prisutna kod 62% obolelih. Nakon prvog ciklusa lečenja, 68,75% bolesnika je postiglo kompletan hematološki odgovor, a stopa ukupnog odgovora na terapiju je bila 100%. Medijana praćenja je bila 51 mesec. Tokom praćenja, kod dva bolesnika je dijagnostikovan nemelanomski karcinom kože, kod jednog karcinom bubrega, a kod jednog bolesnika mijelodisplastični sindrom i karcinom prostate. Osamdeset i osam posto bolesnika je imalo najmanje jednu infekciju, najčešće virusnu. Četiri bolesnika su preminula tokom perioda praćenja. Petogodišnje preživljavanje iznosi 97%. **Zaključak.** Kladribin pokazuje visoku efikasnost u lečenju bolesnika sa triholeukemijom i dovodi do dugotrajnih remisija, uz relativno povoljan bezbedonosni profil.

Ključne reči: kladribin; leukemija vlasastih ćelija; antineoplastični agensi; ishod lečenja

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Introduction

Hairy cell leukemia (HCL), also known as tricholeukemia, is a rare, indolent chronic lymphoproliferative disorder that accounts for 2-3% of all leukemias [1, 2]. Initially described as leukemic reticuloendotheliosis [3, 4], it was later established that the cell of origin is a mature B cell [5]. In 2008, the WHO classification of lymphoid neoplasms distinguished a variant form from the classical form of HCL (cHCL) [6]. cHCL is four to five times more frequent in men than in women [2, 7], and the median age at diagnosis of HCL is approximately 55 years [5, 8].

HCL is characterized by circulating B cells with cytoplasmic projections, pancytopenia, and recur-

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Abbreviations

HCL – Hairy Cell Leukemia
cHCL – classic Hairy Cell Leukemia
HCLv – Hairy Cell Leukemia variant
CD – Cluster of Differentiation
IFN-α – alpha interferon
CR – complete response
PR – partial remission
TTNT – time to next treatment
RFS – relapse free survival
χ^2 – Chi-square
ORR – overall response rate
HBV – Hepatitis B virus
HZV – Herpes zoster virus
SSTI – skin and soft tissue infections
HSV – Herpes simplex virus

rent infections. Early studies reported splenomegaly in more than 90% of patients, but this has become a less prominent feature, presumably due to earlier detection through routine blood examination [9, 10]. A relatively characteristic manifestation of tricholeukemia is monocytopenia in the peripheral blood, though monocytes may be erroneously reported by automated hematology analyzers [10, 11].

The immunophenotypic profile of the leukemic cells is crucial for establishing the diagnosis. The characteristic immunophenotype of CD11c+, CD25+, CD103+, CD123+, along with pan B cell surface antigens (CD19+, CD20+, CD22+), confirms the diagnosis of cHCL [9, 11]. Unlike the HCL variant (HCLv), these cells are intensely stained for CD200 expression and negatively stained for CD27 antigen [11]. A trephine bone marrow biopsy and aspirate are important for assessing the extent of bone marrow infiltration [11].

Historically, splenectomy was the treatment of choice, leading to the elimination of abdominal disturbances and the amelioration of peripheral blood cytopenias [12, 13]. However, with limited therapeutic options, the results were modest, with a median survival time of 4 to 6 years [14]. Since the mid-1980s, therapies have significantly improved with the introduction of three new drugs: alpha interferon (IFN-α) in 1984, and the purine nucleoside analogues pentostatin in 1986 and cladribine in 1990 [15]. However, the use of IFN-α often led to disappointingly low complete response rate, with only partial and short-lived responses [16]. Cladribine (2-chlorodeoxyadenosine) has become universally accepted as the agent of choice in treating HCL, with high CR rates, long-term remissions, minimal toxicity and normal life expectancy [8, 17, 18].

In the relapsed or refractory setting, novel therapeutic options, like rituximab, rapidly accelerated fibrosarcoma B-type/mitogen-activated extracellular signal-regulated kinase (BRAF/MEK) inhibitors, and Bruton Tyrosine Kinase inhibitors, have shown promising results [19].

The aim of this study was to evaluate the efficacy and safety of cladribine in the treatment of cHCL among patients treated at the University Clinical Centre of Vojvodina, with attention particular focus on response rates, survival, infectious complications, and secondary malignancies.

Material and Methods

From September 2013 through December 2023, 34 patients were treated with cladribine at the Hematology Clinic, University Clinical Centre of Vojvodina. The patients were previously diagnosed with cHCL based on the World Health Organization criteria through morphological and immunohistochemical analysis of the bone marrow.

Treatment was initiated in cases of symptomatic organomegaly, declining hematologic parameters (hemoglobin <10 g/dL, platelet count <100,000/mL or absolute neutrophil count <1,000/mL) and/or the presence of systemic symptoms.

A single course of cladribine was administered as a subcutaneous bolus injection at a daily dose of 0.14 mg/kg body weight for five consecutive days. Bone marrow evaluation after treatment was primarily conducted in cases with unclear cytopenia. Responses were determined using standard response criteria regarding complete blood count and splenomegaly, four to six months post-treatment. Complete remission (CR) was defined as near normalization of peripheral blood counts and resolution of organomegaly. Partial remission (PR) was described as more than 50% improvement in cytopenia and organomegaly. Reappearance of hairy cells in peripheral blood or bone marrow was considered a relapse after CR, while progression after PR was defined as greater than 50% increase in residual disease [20].

The clinical database was reviewed retrospectively. Demographic features, as well as clinical and laboratory findings, were collected from medical records. Data regarding secondary malignancies, infectious complications, and survival were supplemented by telephone interviews with the patients or their physicians.

The study was approved by the University Clinical Center Ethics Committee and conducted in accordance with the Declaration of Helsinki.

Data were analyzed using descriptive statistics. Categorical variables were summarized as frequencies and percentages, while continuous variables were summarized as median values and range. Since HCL is an indolent disease that does not necessarily require immediate treatment in case of relapse, time to next treatment (TTNT) was considered a more relevant parameter than relapse-free survival (RFS). TTNT was measured from the date of treatment initiation to the date of retreatment for patients achieving a CR or PR. Observations of TTNT were censored at the date of the last contact for patients with no report of relapse or retreatment who were last known to be alive. Overall survival

Table 1. Patient characteristics (n=34)
Tabela 1. *Karakteristike obolelih (n=34)*

Median age at diagnosis, years (range)/*Medijana starosti pri dijagnozi, godine (opseg)*	52 (30–83)
Median age at the time of treatment with cladribine, years (range) *Medijana starosti u vreme lečenja kladribinom, godine (opseg)*	53 (38–83)
Male : female (n/n) (ratio)/*Muškarci : žene (n : n) (odnos)*	(26:8) (3.25:1)
Symptomatic disease, n (%)/*Simptomatska bolest, n (%)*	17 (50%)
Pancytopenia, n (%)/*Pancitopenija, n (%)*	22 (64.7%)
Splenomegaly, n (%)/*Splenomegalija, n (%)*	21 (61.76%)
Hemoglobin at baseline, median (range) (g/L) *Hemoglobin pred započinjanje lečenja, medijana (opseg) (g/L)*	110 (71–156)
Platelet count at baseline, median (range) ($x10^9$/L) *Broj trombocita pred započinjanje lečenja, medijana (opseg) ($x10^9$/L)*	64 (17–269)
White blood cell count at baseline, median (range) ($x10^9$/L) *Broj leukocita pred započinjanje lečenja, medijana (opseg) ($x10^9$/L)*	2.69 (0.65–20.2)
Follow-up (months), median (range)/*Praćenje (meseci), medijana (opseg)*	51 (0.3–148)

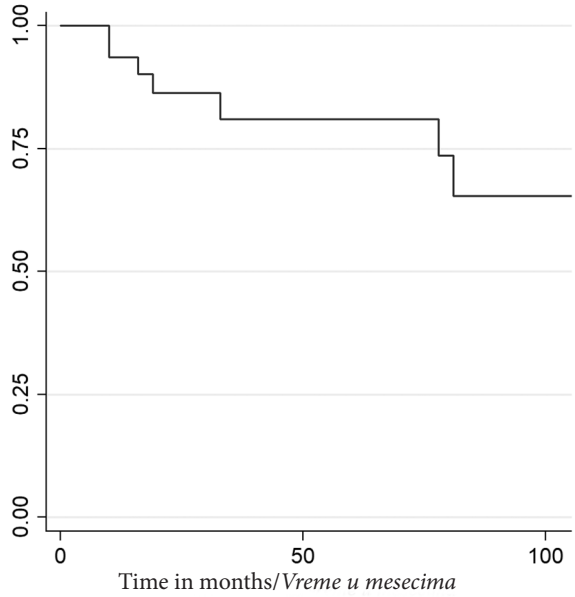
was measured from the date of diagnosis to the event of death. Patients last known to be alive were censored. Overall survival was estimated using Kaplan-Meier analysis. Statistical analyses were performed using Stata statistical software. Chi-square test (χ^2) was used to determine if there was a statistically significant difference in complete response rates between patients treated with cladribine frontline and second-line, with a p-value of <0.05 was considered to be statistically significant.

Results

We report on 34 cHCL patients treated with cladribine, of whom 32 were evaluable for response. The median age at diagnosis was 52 years (range 30–83). Clinically, 62% of patients presented with splenomegaly, 65% had pancytopenia and 50% were symptomatic. Patient characteristics are presented in **Table 1.** Bone marrow biopsy histological findings at diagnosis were available in 27 (79%) cases and showed a 64% medullary infiltration by hairy cells, on average.

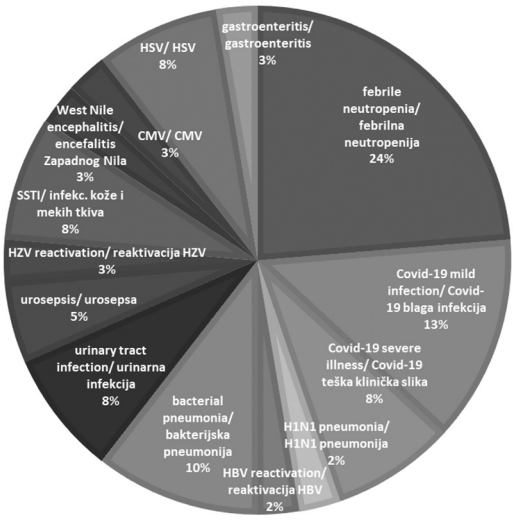
The median age at the time of cladribine administration was 53 years (range 38 to 83). Cladribine was administered as a first-line treatment to 20 (59%) patients and as a second-line treatment in 14 (41%) patients (after IFN-α). It appeared to be equally effective as both first- or second-line therapy (χ^2=0.22, p=0.63). Among the 32 patients evaluable for response, 22 (68.75%) achieved CR after one cycle of cladribine. The overall response rate (ORR) was 100%.

Eight relapsing patients received another course of cladribine, 10–118 months after the first cycle (median 26 months), and one of them received a third cycle as well. One patient was treated with rituximab and vemurafenib 26 months after the second course of cladribine, while rituximab alone was administered in another case, eight years after the cladribine retreatment. Follow-up period ranged from 0.3 to 148 months (median follow-up 51 months). The Kaplan-Meier progression-free survival (PFS) estimation curve is shown in **Graph 1.**

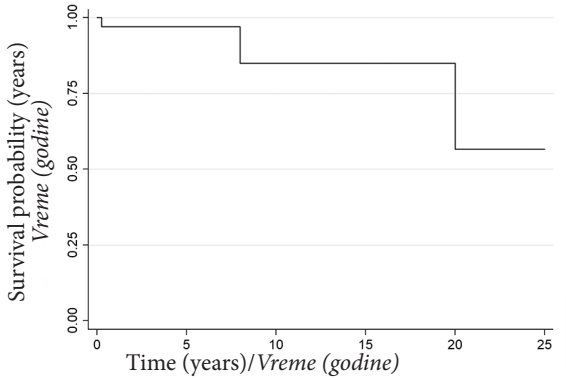


Graph 1. RFS probability
Grafikon 1. *Verovatnoća preživljavanja bez relapsa*

During the follow-up period, two patients were diagnosed with non-melanoma skin cancers, one patient with renal cell carcinoma, and one with myelodysplastic syndrome and prostate cancer. Eighty-eight percent of patients experienced at least one infection during follow-up, with viral infections being the most frequent complications **(Graph 2).** Four out of 34 patients died during the follow-up period – two of them due to viral pneumonia (H1N1 and Covid-19), one due to uncontrolled hairy cell leukemia, and one due to Gram-negative bacterial sepsis, occurring a week after therapy administration. The 5-year overall survival rate was 97% **(Graph 3)**.



Graph 2. Infections detected during the follow-up period. *HBV – Hepatitis B virus; HZV – Herpes zoster virus infection; SSTI – skin and soft tissue infections; CMV – Cytomegalovirus infection; HSV – Herpes simplex virus*
Grafikon 2. *Infekcije zabeležene tokom perioda praćenja. HBV – Hepatitis B virus; HZV – Herpes zoster virusna infekcija; SSTI – infekcija kože i mekih tkiva; CMV – citomegalovirusna infekcija; HSV – Herpes simplex virus*



Graph 3. Overall survival
Grafikon 3. *Ukupno preživljavanje*

Discussion

In this study, as expected based on previous observations [2, 7, 21], there is a higher proportion of men than women among the patients with cHCL. However, the ratio is slightly skewed towards women, which might be a consequence of the relatively small cohort size, constituting the biggest limitation of the analysis. Most of the patients were between 50 and 70 years old at the time of diagnosis and treatment, aligning with commonly reported data in the literature [2, 15, 17].

Symptomatic disease (B symptoms and/or symptomatic organomegaly) was present in half of our patients before cladribine initiation. The available literature does not specify whether patients had symptoms before the therapy. However, a recent study from Czech Republic reported that indication for first-line treatment was the presence of B symptoms and symptomatic organomegaly in 13.7% and 42.9% of patients, respectively [22]. While these results are similar to ours, they are not entirely comparable due to differences in reporting. Regarding splenomegaly, several studies report similar results, with 67% (among 45 subjects) and 66.5% (among 221 subjects) of patients having splenomegaly at baseline [17, 23]. An Italian study published two years ago, which included patients treated between March 1991 and May 2019 across 18 hematology centers, reported a slightly lower prevalence of splenomegaly (46.9% of 513 patients) [21]. An even lower prevalence (33.3% of 123 patients) was observed among patients treated in the French region of Western Normandy between 1996 and 2016 [2]. These differences could be attributed to variations in study group sizes and the timing of diagnosis. In the French study, 20.3% of patients had pancytopenia [2], but other literature often does not specify the number of patients with pancytopenia, or specifies only mean values and range of individual parameters, making direct comparisons challenging [8, 9, 17, 21, 23, 25].

In our cohort, the ORR to cladribine was 100%, with 68.75% achieving CR and 31.25% achieving PR. Similar data can be found in other studies, with ORR up to 100% and a variable proportion of CR ranging from 48.6 to 95% [17, 21, 23–25]. According to current recommendations, response assessment includes evaluating hematologic parameters, physical examination with spleen size estimation, and bone marrow biopsy, typically delayed for 4 to 6 months after drug administration is completed [11]. The literature observes that the CR percentages increase over time, from 80% after 3-4 months to nearly 100% after 6 months [17, 26]. Therefore, inconsistent results among studies can partially be explained by differences in the timing and method of response assessment, which are usually not clearly stated. The retrospective nature of our study is a significant drawback.

In our study, TTNT ranged from 10 to 118 months (median 26 months) after the first cycle of cladribine. Similar results were published in 2003, where 209 patients werw treated with cladribine and had at least 7 years of follow-up from April 1986 to November 2000. In these patients, time to relapse after the first course of cladribine ranged from 8 to 118 months [25]. Other studies reported different results, with a median TTNT ranging from 28 to 147 months [2, 27]. Notably, the median TTNT of 28 months was observed in a study targeting patients aged 70 and over, where the CR percentage was lower than in most studies (71%). Older age at diagnosis has been associated with worse prognosis in other studies as well [28].

Non-melanoma skin cancers are the most common secondary malignancies in our group, consistent with other studies that followed HCL patients for several decades after cladribine administration. Secondary malignancies developed in about 20% of these patients [23, 25]. The proportion is lower in our cohort – four out of 34 (11.7%), but the sam-

ple size is also much smaller compared to studies that included around 200 patients each [23, 25].

Purine nucleoside analogs are known to cause serious myelosuppression, and a high risk of severe infections, particularly in the initial treatment phase. The incidence of infections ranges from 30 to 50% [21, 29], with respiratory tract infections being the most common [21, 30]. The higher rate of infections in our study may partly be explained by the follow-up period, which included the COVID-19 pandemic.

The 5-year and 10-year overall survival predicted here does not significantly differ from those reported in other studies [21, 23, 31].

With modern therapeutic options, HCL has transitioned from a deadly illness to a disease with a favorable prognosis, where life expectancy among patients is similar to the general population [23, 31, 32]. However, increased susceptibility to infections, both in the initial phase and during post-therapeutic bone marrow suppression, necessitates great caution, particularly regarding preventive measures and timely initiation of treatment with purine analogs before blood parameters decline to dangerous levels or before a patient acquires an active infection. The updated Hairy Cell Leukemia Foundation guidelines consider off-label treatment options with vemurafenib for patients with HCL who have pancytopenia and an active uncontrolled infection [33, 34]. The use of myeloid growth factors should be considered individually for each patient with an active infection [11, 21]. Live virus vaccines should be avoided, though patients may receive vaccines containing inactivated viral pathogens, despite limited evidence on the development of an adequate immune response in these patients [11].

Conclusion

Although the number of patients in our cohort is a limiting factor, we can conclude that cladribine demonstrates high efficacy in the treatment of hairy cell leukemia patients, leading to long-term remissions with a relatively favorable safety profile. Nowadays, these patients have near-normal life expectancy, comparable to the general population. However, due to their increased risk of developing secondary malignancies, long-term follow-up is mandatory. The challenge of managing infections remains a unique aspect of treating these patients. For those who are relapsed or refractory to purine nucleoside analogs, several targeted drugs have shown considerable promise in clinical trials.

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