

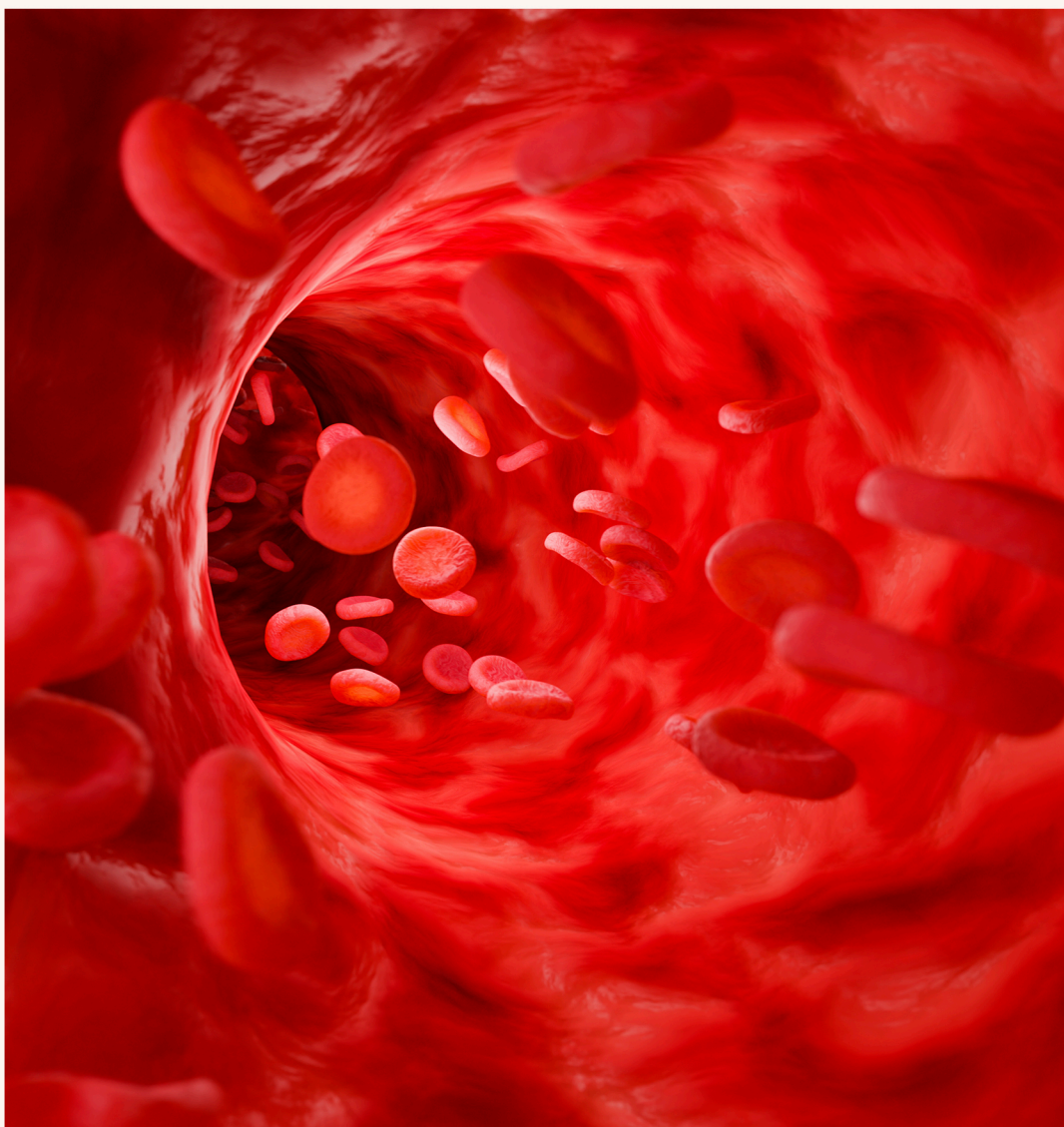
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# Personalized Management of Patients with Dual Malignancies: Multiple Myeloma and a Solid Tumor

**Hadil Abubakr, Loredana Cirlan, Sinziana Barbu, Larisa Zidaru, Ruxandra Draghici, D. Coriu, Sorina Bădeliță**

*The coexistence of multiple myeloma (MM) and solid tumors (whether preceding, concomitant, or subsequent to the diagnosis of MM) poses significant clinical challenges.*

*This reflects therapeutic realities in routine practice: patients treated under national protocols or at academic oncology centers across different time periods, exposed either to conventional cytotoxic regimens or targeted therapies, in parallel with MM-specific approaches (ImiDs, proteasome inhibitors, monoclonal antibodies, and in selected cases, autologous stem cell transplantation). The diversity of tumor types observed (breast, colorectal, lung, renal, prostate) highlights the necessity of tailoring therapeutic decisions according to diagnostic chronology, cumulative toxicities, comorbidities, and patient-centered goals.*

*The rising incidence of MM, coupled with increasing life expectancy and prolonged exposure to oncogenic factors, has resulted in a substantial population of patients presenting with both MM and solid tumors. This dual pathology creates major clinical challenges: overlapping toxicities, restricted therapeutic options, and the lack of integrated treatment protocols.*

*In our clinical experience, we analyzed 47 patients with MM and associated solid tumors (solid malignancies diagnosed between 2004–2025; MM diagnosed between 2009–2025). The distribution was heterogeneous: 14 patients (30%) developed a solid tumor prior to MM, 12 (25%) were diagnosed concomitantly, and 21 (45%) developed solid tumors after MM. The most frequent localizations were colorectal cancer (~25%), breast cancer (~20%), lung cancer (~15%), and urologic neoplasms (~15%), while other sites (thyroid, stomach, melanoma, pancreas) accounted for <10%.*

*Therapeutic interactions produced notable cumulative toxicities: severe myelosuppression (G3–4 neutropenia) in ~40% of patients, peripheral neuropathy (G2–3) in ~25%, renal dysfunction requiring dose adjustments in ~30%, and thromboembolic events in ~15%, particularly in patients treated with ImiDs. The principal therapeutic conflicts identified were cumulative myelosuppression (solid tumor cytostatics combined with melphalan/lenalidomide), peripheral neuropathy (bortezomib with taxanes or platinum compounds), renal impairment (MM-related and aggravated by nephrotoxic agents such as cisplatin), and an enhanced thrombotic risk (ImiDs in the context of a proinflammatory oncologic state).*

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# Central Nervous System Manifestations of Multiple Myeloma - A Case Series and Comprehensive Literature Review

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*Central nervous system (CNS) involvement in Multiple Myeloma (MM) represents an aggressive extramedullary manifestation of the disease, which is often a real challenge for the clinicians, as the neurological symptoms could easily overlap those related to hypercalcemia, uremia, high viscosity of the blood or treatment related neuropathy.*

*A retrospective study was conducted at Fundeni Clinical Institute from Bucharest, aiming to identify and systematically analyze a series of clinical cases diagnosed with extramedullary disease. We have identified 6 out of 1175 patients with CNS involvement in our Institute's Database between 2019 and 2024.*

*The diagnosis of meningeal myelomatosis was established through cerebrospinal fluid analysis, including cytology, immunophenotyping, immunofixation, whereas CNS plasmacytomas were confirmed by CT-guided biopsy followed by immunohistochemistry evaluation. All of the patients underwent MRI for disease assesment as well. Chemotherapy, including intrathecal administration, and radiotherapy were used in management of these patients.*

*We aim to contextualize our outcomes in managing the disease by comparing the results that are already stated in the literature and to also provide a review of the existing articles. Standard practice dictates that every patient should receive a tailored therapeutic approach, and even though survival is generally poor, we aim to recognize the situations where survival can be increased.*

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# Allogenic Stem Cell Transplantation in Hypomethylating Agents + Venetoclax Treated Patients with Acute Myeloid Leukemia in Fundeni Clinical Institute

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*Background:* Hypomethylating agents, such as Azacitidine and Decitabine, in combination with Venetoclax have become now a standard first line therapy for patients diagnosed with Acute Myeloid Leukemia (AML). This type of treatment has been approved by EMA (European Medicines Agency) in May 2021 and reimbursed by NHII (National Health Insurance Institution) in Romania since March 2023.

*Although initially some of the patients were considered ineligible for intensive chemotherapy, a subset of them have achieved disease control and an improved performance status, enabling them to go through the allogeneic hematopoietic stem cell transplantation.*

*Materials and methods:* We conducted a retrospective, single center study that aimed to evaluate the demographic characteristics, as well as the clinical and biological evolution of patients treated with hypomethylating agents and Venetoclax in Fundeni Clinical Institute of Bucharest.

*Results:* Between March 2022 and August 2025, a total of 415 patients diagnosed with Acute Myeloid Leukemia were evaluated in our department. Of these, 116 received treatment consisting of hypomethylating agents and Venetoclax, aiming to achieve complete remission with consolidation through allogeneic stem cell transplantation. (n=10%)

*Conclusion:* Currently, the use of this modern treatment for AML as a first line therapy represents just a checkpoint on the path to the final destination: the allogeneic stem cell transplantation.

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# Allogeneic Stem Cell Transplantation in Acute Myeloid Leukemia: The Experience of the Iasi Regional Oncology Institute

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*Background:* Allogeneic stem cell transplantation (allo-SCT) remains the only curative treatment option for acute myeloid leukemia (AML) patients. We present the outcomes of 59 AML patients who underwent allo-SCT at our center.

*Materials and methods:* We retrospectively analyzed patients transplanted between 2019 and 2024. Baseline characteristics included age, sex, ELN 2022 risk, disease status at transplant (CR1, CR2, active disease), donor type, GVHD prophylaxis. Outcomes evaluated were engraftment, acute and chronic GVHD, cumulative incidence of relapse (CIR), non-relapse mortality (NRM), overall survival (OS), disease-free survival (DFS). Survival was estimated by the Kaplan–Meier method.

*Results:* The median age was 44 years. 84.7% of patients were transplanted in CR1. Donors included: matched sibling 42.4%, unrelated 49.2%, and haploidentical 8.5%. Median time to neutrophil and platelet engraftment was 19 and 15 days, respectively. Incidence of grade II–IV acute GVHD was 16.9%, and chronic GVHD 25.4%. At a median follow-up of 26 months (95% CI: 32–44), OS and DFS were not reached. The 2-year CIR and NRM were 28% (CI, 16–41%), and 3.5% (95% CI, 0–8%), respectively (median not reached). Patients transplanted in CR1 showed the best outcomes (mean OS 88.7 months; 2-year DFS: 74%), while CR2 patients had inferior results (mean OS 33.5 months; 2-year DFS: 40–45%). Differences were significant (OS  $p=0.004$ ; DFS  $p=0.007$ ).

*Conclusions:* Our single-center experience confirms that allo-SCT is feasible and effective in AML, with outcomes comparable to international reports. The disease status at the moment of transplantation remains the most powerful prognostic factor.

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# Pleuro-Pulmonary Extramedullary Plasmacytomas in Multiple Myeloma: What 15 Years of Clinical Practice Have Taught Us

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*Extramedullary disease (EMD) in multiple myeloma (MM) is rare and is associated with a poor prognosis. Thoracic involvement—including pulmonary and pleural plasmacytomas, as well as myelomatous effusion—is exceptionally uncommon.*

*We conducted a retrospective analysis of MM patients diagnosed at Fundeni Clinical Institute from 2010 to 2025. We identified 34 cases of pleuro-pulmonary EMD through imaging, cytology, immunophenotyping, or histopathology. Out of 2,012 MM patients, the incidence of pleuro-pulmonary EMD was 1.6%. The median age of patients was 58 years, with an equal gender distribution. EMD was present at diagnosis in 26.5% of cases and at relapse in 73.5%. The most common presentation combined pleural infiltration with effusion, accounting for 70.6% of cases. Adverse features included  $\beta 2$ -microglobulin levels greater than 3.5 mg/L in 82% of patients, elevated LDH levels in approximately 50%, and high-risk cytogenetic abnormalities (such as  $\text{del}(17p)$ ,  $t(4;14)$ ,  $t(14;16)$ ,  $t(11;14)$ , and  $1q$  gain). The median overall survival (OS) from the onset of EMD was 16 months, with a 2-year OS rate of 25% and no 5-year survivors. The median progression-free survival (PFS) was 9 months.*

*Pleuro-pulmonary EMD represents a highly aggressive subset of MM with extremely poor outcomes, particularly at relapse. There is an urgent need for novel therapies and individualised treatment strategies.*

*Keywords: multiple myeloma, extramedullary disease, pleuro-pulmonary involvement, prognosis*

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# Clinical and Prognostic Characteristics of Patients with Systemic T-Cell Lymphomas: A Single-Center Experience (Fundeni Clinical Institute, 2015–2024)

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*Objective:* Mature T-cell lymphomas represent a heterogeneous group of neoplasms with low incidence, aggressive biological behavior, and poor prognosis. In the absence of standardized national registries, single-center studies provide valuable insights into the clinico-biological characteristics and outcomes of these patients. The objective of this study was to retrospectively analyze patients diagnosed and treated at the Fundeni Clinical Institute between 2015–2024, with a focus on histologic distribution, prognostic factors, and overall survival (OS).

*Materials and methods:* This was a retrospective, descriptive, and analytical study including 149 consecutive patients histopathologically diagnosed with systemic mature T-cell lymphomas. The statistical analysis comprised 132 eligible cases. Demographic data, biological parameters, disease stage, treatment, and OS were collected. Survival was assessed using the Kaplan–Meier method, and curve comparisons were performed with the Log-Rank test ( $p < 0.05$ ).

*Results:* The median age at diagnosis was 57.2 years ( $SD \pm 13.8$ ), with male predominance (59.9%). Histologic distribution was as follows: PTCL-NOS 30%, ALCL (ALK+ and ALK–) 28%, TFH 21%, ATLL 20%.

OS varied significantly between histologic subtypes ( $p < 0.001$ ): ALCL demonstrated the most favorable outcome (median not reached, mean OS ~72 months), whereas ATLL showed the poorest survival (median 6.5 months); TFH had a median OS of 26.5 months and PTCL-NOS of 16.6 months.

Significant adverse prognostic factors were: ECOG score  $\geq 2$  (median 9 vs 46.4 months,  $p < 0.001$ ), B symptoms (11.5 vs 59.3 months,  $p = 0.006$ ), advanced Ann Arbor stage III–IV (14.3 months vs median not reached,  $p = 0.002$ ), bone marrow involvement (5.9 months vs median not reached,  $p < 0.001$ ), splenomegaly (9.1 months vs median not reached,  $p < 0.001$ ), and hepatomegaly (9.2 vs 41.7 months,  $p = 0.002$ ).

Biological markers associated with reduced OS included: thrombocytopenia (5.4 months,  $p < 0.001$ ), eosinophilia (9.4 months,  $p = 0.021$ ), LDH  $\geq 2 \times ULN$  (6.9 months,  $p < 0.001$ ), hypoalbuminemia (6 months,  $p < 0.001$ ), elevated CRP (13.1 months,  $p = 0.004$ ), elevated creatinine (9.8 months,  $p = 0.004$ ), elevated bilirubin (4.2 months,  $p = 0.036$ ), D-dimers  $\geq 2 \times ULN$  (5.6 months,  $p = 0.006$ ), and increased AST (8.3 months,  $p = 0.001$ ). Low fibrinogen correlated with a markedly poor prognosis ( $p < 0.001$ ). Hypercalcemia was associated with reduced OS (–1.5 months), without statistical significance ( $p = 0.206$ ).

*Conclusions:* This study confirms the clinico-biological heterogeneity of mature T-cell lymphomas and highlights the significant impact of histologic subtype, functional status, B symptoms, advanced stage, and biological markers on overall survival. These findings emphasize the need for national registries and more refined risk stratification to optimize the management of patients with mature T-cell lymphomas.

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# Interleukin Profile (IL-2, IL-10, And IL-35) in Patients with Mature T-Cell Lymphomas at Diagnosis

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*Objective: Plasma levels of interleukins IL-35, IL-10, and IL-2 may reflect the immune status and hold prognostic significance in mature T-cell lymphoid neoplasms. This study evaluates cytokine levels at diagnosis and explores their potential integration into prognostic scoring systems.*

*Materials and methods: Plasma samples from 23 patients with mature T-cell lymphomas (subtypes: ATLL, ALK-negative ALCL, PTCL-NOS, MEITL, nasal NK/T-cell lymphoma, T-helper cell lymphoma) and two healthy controls were analyzed. Quantification of IL-2, IL-10, and IL-35 was performed using standardized ELISA assays.*

*Results: Elevated IL-10 levels were observed in a subset of patients, supporting its role in establishing an immunosuppressive microenvironment, with potential adverse prognostic implications. IL-2 levels were varied, in some cases decreased, which may indicate functional exhaustion of T cells. IL-35, a key immunosuppressive cytokine, was detected in most patients, with elevated concentrations in selected cases, underscoring its contribution to the tumor-associated immunosuppressive milieu.*

*Conclusions: The cytokine profile, defined by increased IL-10 and IL-35 levels, supports their involvement in the unfavorable clinical course of mature T-cell lymphomas. The variability of IL-2 may reflect the degree of immune activation and exhaustion. Integrating these immunologic parameters with established clinico-biological factors may improve risk stratification and guide therapeutic strategies in mature T-cell lymphoid neoplasms.*

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# Next-Generation Sequencing in Acute Myeloid Leukemia: The Prognostic Value of Mutation Categories in A Real-World Single Center Cohort

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*Background: The clinical impact of mutational profiles in acute myeloid leukemia (AML) patients is ill-defined in real-world settings, irrespectively of treatment intensity.*

*Methods: 52 AML patients diagnosed at the Iasi Regional Oncology Institute were included in this retrospective study and risk stratified according to the 2022/2024 ELN risk systems. All patients underwent targeted NGS (panel>100 genes). Mutations were categorized as TP53, NPM1, myelodysplasia-related, epigenetic, spliceosome, signalling or "other" (IKZF, STAT3, KMT2A, ETV6, CREBBP, CBL, ZBTB7A). Overall survival (OS) and disease-free survival (DFS) were estimated using Kaplan–Meier analysis. Cox regression models were used for multivariate analyses.*

*Results: 51.9% of patients received intensive induction and 48.1%-Venetoclax+Azacitidine. The overall complete remission (CR) rate was 65.4%. Median OS was 24 months (95% CI: 11.2–36.8), significantly longer in patients receiving intensive induction compared to non-intensive therapy (27.5 vs 12.1 months,  $p=0.026$ ). Achievement of CR predicted superior OS (HR 0.24,  $p=0.001$ ). In multivariate analysis, ECOG  $\geq 2$  (HR 2.7,  $p=0.046$ ) and failure to achieve CR (HR 4.1,  $p=0.003$ ) independently predicted inferior OS, while mutational subgroups did not retain significance. Median DFS was 14.0 months. High mutational burden ( $\geq 4$  mutations) was associated with inferior DFS (5.0 vs 23.0 months,  $p<0.001$ ). Patients with mutations labelled as "other" had significantly shorter DFS (9.0 vs 23.0 months,  $p=0.010$ ).*

*Conclusions: In this real-world cohort, OS was primarily determined by treatment intensity, ECOG status, and CR achievement. DFS analysis identified mutational complexity and "other" rare mutations as predictors of early relapse, underscoring the importance of integrating NGS findings into risk stratification.*

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# Clinical Characteristics and Outcomes of Acquired Hemophilia A: A 10-Years Single- Centre Experience

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*Purpose: Acquired hemophilia A is a rare condition caused by the appearance of autoantibodies against circulating factor VIII. The severity of bleeding can be severe, and in 8-22% of cases the disease can be fatal in the absence of early diagnosis and specific treatment. The aim of the current study is to analyze the cases of acquired hemophilia A in terms of clinical characteristics and outcome of treatment.*

*Material and method: We performed a retrospective study that included 35 patients diagnosed with acquired HA from the records of the Hematology Clinic of Fundeni Clinical Institute between 2015 and 2025.*

*Results: Patients ranged from 18 to 91 years of age at diagnostic (mean age 58 years); 63.8% were female, 38.9% had no underlying pathology, 19.4% were associated with a neoplastic condition, 22.2% had an autoimmune disease, and 19.4% were diagnosed postpartum. All patients presented with hemorrhagic manifestations at onset, 66.7% had severe bleeding requiring hemostatic treatment and transfusions (50%). 36% achieved complete remission after first-line immunosuppression, 36% required escalation of therapy by combining other drugs, ultimately 66.7% of patients being cured. 41.6% patients were lost to follow-up, and 44.4% patients died of hemophilia or associated pathologies.*

*Conclusions: Our study provides a comprehensive database that supports other centers with less experience, so that such patients benefit from a prompt diagnosis and appropriate and effective treatment.*

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# **Tp53 Double-Hit in Multiple Myeloma: Insights from an Ongoing Study**

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*Background: Multiple myeloma (MM) is a genetically heterogeneous plasma cell malignancy, with cytogenetic abnormalities significantly impacting prognosis and therapeutic decisions. Comprehensive genomic profiling, including FISH and targeted molecular analyses, is essential for risk stratification and identification of high-risk patients, such as those with TP53 double-hit events.*

*Methods: Fifty MM patients at various disease stages (newly diagnosed, relapsed, refractory) were analyzed. Clinical data were collected, and patients were investigated using both FISH analysis for recurrent cytogenetic abnormalities and MLPA for TP53 deletions and CHEK2 variants, aimed to evaluate potential double-hit events.*

*Results: FISH analysis revealed a broad spectrum of recurrent abnormalities, including del(17p), IGH translocations, and chromosomal gains, with variable distribution across disease stages. MLPA analysis identified genetic alterations with potential prognostic impact, including TP53 deletions and CHEK2 variants, with some cases suggestive of double-hit events. High-risk abnormalities were more frequently observed in relapsed or refractory patients.*

*Conclusion: These preliminary findings highlight the diversity of cytogenetic and molecular abnormalities in MM. Integration of forthcoming MLPA results will enable more comprehensive identification of high-risk patients, including TP53 double-hit cases, thereby improving prognostic stratification and therapeutic guidance.*

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# Chronic Lymphocytic Leukemia with Cerebral Location Associated with High Risk Thrombophilia: Diagnosis and Therapeutic Challenges, Data from Literature in Correlation with Clinical Practice

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*Purpose: Chronic lymphocytic leukemia (CLL) represents a lymphoproliferative disease with indolent evolution in which specific treatment is initiated in the presence of specific clinical and/or biological criteria that are well defined. However there are atypical cases outside the classical paradigm that pose a challenge between establishing diagnosis and starting treatment. This paper brings out atypical manifestations of CLL in the context of cerebral determination and high risk thrombophilia, exploring the discrepancies between the absence of standard CLL criteria and severe clinical manifestation*

*Materials and methods: The point of this paper is to outline the insufficient data in literature through analyzing a clinical case with atypical debut, underlining the need of an multidisciplinary approach and the reduced applicability of standard criteria in front of a severe clinical case with non typical debut.*

*Results: We report the case of a male patient 54 years of age diagnosed with CLL stage A Binet/II RAI without criteria for initiating treatment that had a debut with neurological symptoms and deep vein thrombosis in multiple sites. Imaging studies and spine fluid analysis confirmed the presence of a cell population CD43+, CD79b -, CD20dim, CD19+, CD5+ ( phenotypic aspect identical to the peripheric one). Thrombophilia screening identified concomitant presence of Leiden factor V and factor II mutation, with positive familial history for thrombotic events.*

*Conclusion: This atypical case outlines the fact that the presence of CLL without formal criteria for treatment initiation does not rule out a severe evolution and the rare presence in the nervous system can indicate a major treatment indication. Moreover the coexistence of a prothrombotic state adds additional challenges to the management of the patient in matters of oncological treatment and thrombotic prophylaxis.*

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# Primary Medullary Follicular Lymphoma Associated with Grade III Myelofibrosis: A Rare Case Report

**Gabriela Diana Cantor, Luminița Ocroteală, Amelia-Maria Gaman**

*Purpose: Primary medullary follicular lymphoma (PMFL) is a rare subtype of follicular lymphoma limited to the bone marrow, often without peripheral lymphadenopathy. Its association with high-grade myelofibrosis (MF) is extremely uncommon, presenting a diagnostic and therapeutic challenge due to overlapping features with other bone marrow disorders.*

*Materials and methods: We report a case of a 63-year-old female presenting with type B symptoms with latent onset around 6 months before presentation. Laboratory evaluation revealed severe pancytopenia (leukocytes 900/mm<sup>3</sup>, haemoglobin 6 g/dl, platelets 18.000/mm<sup>3</sup>), prompting a bone marrow biopsy. Histopathological examination and immunohistochemistry confirmed PMFL with grade 3 MF, evidenced by increased reticulin and collagen fibrosis. Testing for myeloproliferative neoplasms and other causes of secondary MF was negative, supporting the diagnosis of primary lymphoma.*

*Results: While PMFL is generally indolent, the presence of high-grade MF in this case suggests a more complex clinical trajectory. This combination of PMFL and severe fibrosis complicates diagnosis and management, emphasizing the role of bone marrow biopsy and immunophenotyping in distinguishing this rare lymphoma from other myelofibrotic conditions.*

*Conclusion: This case highlights a rare presentation of PMFL with grade III MF, underscoring the importance of comprehensive diagnostics in atypical myelofibrosis and contributing to the limited literature on this unique clinical entity. Further studies are needed to guide the management of this association.*

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# Rapid Molecular Diagnosis as Standard of Care in Infections Associated with Acute Myeloid Leukemia Patients

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*Objective: Infections are the main cause of non-malignant mortality in hematologic patients, and the elevated antimicrobial resistance in Romania amplifies this risk. The study aims to define a standard of care for the rapid diagnosis of infections in patients with acute myeloid leukemia, by integrating molecular tests and characterizing the local microbiological profile.*

*Materials and methods: The authors initiated during 2024–2025 a unicentric observational study, both retrospective and prospective, on 100 patients hospitalized in the Hematology Department I of Colentina Clinical Hospital; the preliminary analysis included 65 patients. Collected samples (blood cultures, EDTA blood, sputum, tracheobronchial aspirates and lavage) were tested using the BioFire® Torch system: the BCID2 (blood culture identification 2) panel for the identification of bacteria, fungi, and resistance genes (CTX-M, OXA-48-like, KPC, VIM) and the Pneumonia Plus panel for bacterial, viral, and fungal respiratory pathogens. Determinations were also performed using qualitative RT-PCR for Mycobacterium tuberculosis and quantitative RT-PCR for Cytomegalovirus. Molecular results were correlated with clinical data and epidemiological analysis.*

*Results: Patients frequently presented 1–2 infectious episodes, often requiring second-line antibiotic therapy (meropenem, linezolid, ceftazidime-avibactam, tigecycline, vancomycin). Molecular tests identified pathogens such as Escherichia coli, Streptococcus pneumoniae, Haemophilus influenzae, Streptococcus agalactiae, Mycoplasma pneumoniae and Aspergillus. Infectious mortality was documented in severely immunocompromised patients. Results were available within 2–48 hours, allowing early adjustment of empirical therapy.*

*Conclusions: Molecular tests, due to their accuracy and short processing time, optimize diagnosis, reduce hospitalization duration and costs, limit the escalation of antibiotic therapy and may decrease mortality and the emergence of antimicrobial resistance.*

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# Interdisciplinary Collaboration Improves Early Diagnosis of Multiple Myeloma in Patients with Renal Manifestations

**Bianca Constantin<sup>1</sup>, Corina Ene<sup>2,3</sup>, Ioana Miller<sup>2,3</sup>, Mădălina Stăncescu<sup>2,3</sup>, Sorina Bădeliță<sup>1,2</sup>**

*Objective: Multiple myeloma (MM) is a malignant plasma cell disorder, with renal involvement frequently representing one of the earliest clinical manifestations. This retrospective observational study analyzes the diagnostic pathway of patients with suspected MM initially assessed in nephrology departments and highlights the impact of interdisciplinary collaboration among nephrologists, general practitioners, and hematologists in achieving an accurate and timely diagnosis.*

*Materials and methods: We conducted a retrospective observational study including a case series from two referral centers: Carol Davila Clinical Nephrology Hospital and Fundeni Clinical Institute. Patients presenting with renal dysfunction who were subsequently diagnosed with MM were evaluated. Clinical, biochemical, and paraclinical data were analyzed, with emphasis on the role of serum protein electrophoresis (SPEP) in early diagnostic orientation. A p-value will be calculated to determine statistically significant correlations.*

*Results: Preliminary findings show that renal impairment is frequently present at the time of MM diagnosis, and integrating nephrological evaluation into the diagnostic algorithm significantly improves early case identification. Statistical analysis, including p-value calculation, will confirm the strength of this association.*

*Conclusions: Integrating nephrologists and general practitioners into the diagnostic pathway of MM is essential. Early implementation of SPEP in nephrological evaluation may substantially enhance diagnostic accuracy and reduce delays in initiating treatment.*

*Keywords: multiple myeloma, renal impairment, serum protein electrophoresis, early diagnosis, interdisciplinary approach*

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# Acute B Lymphoblastic Leukemia with Mll Gene Rearrangements – A Single-Center Retrospective Analysis

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*Objective: Acute B lymphoblastic leukemia (B-ALL) with MLL gene rearrangements is a high-risk subtype, associated with aggressive clinical features and frequent relapses.*

*Materials and methods: This single-center retrospective study includes patients diagnosed with B-ALL between 2014–2024, with positive molecular findings for MLL-AF4/KMT2A-AF4 mutations or MLL rearrangements detectable by FISH.*

*Results: The cohort included 20 patients, median age 44.5 years, with a female-to-male ratio of 1.5:1. Seventeen patients had MLL-AF4/KMT2A-AF4 mutations, while three showed MLL rearrangements on FISH but were negative on molecular testing, suggesting atypical or undetectable fusion partners. Six patients had extramedullary involvement, most commonly in the central nervous system (4 cases), followed by the ovary and spine (1 case each).*

*Seven patients expressed the NG.2 surface marker, associated with MLL rearrangements, steroid resistance, and early relapse.*

*Eight patients underwent allogeneic hematopoietic stem cell transplantation, two during first complete remission. Median survival was 9 months.*

*Conclusions: B-ALL with MLL gene rearrangements poses significant therapeutic challenges due to early relapse and extramedullary disease. Allogeneic stem cell transplantation should be considered in first remission when a donor is available.*

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# Single-Center Experience with Inotuzumab Ozogamicin in Relapsed/Refractory Acute Lymphoblastic Leukemia: Data From Clinical Practice

**Cristina Enache<sup>1</sup>, Alexandra Ghiaur<sup>1</sup>, B. Ionescu<sup>1</sup>, Roxana Isabela Hirjan<sup>1</sup>,  
Maria Camelia Stancioaica<sup>1,2</sup>, Aurelia Tatic<sup>1,2</sup>, D. Coriu<sup>1,2</sup>**

*Background: Relapsed/refractory (R/R) acute lymphoblastic leukemia (ALL) in adults remains a therapeutic challenge, characterized by a low rate of complete remission, poor prognosis, and chemoresistance. Inotuzumab ozogamicin (INO), an anti-CD22 monoclonal antibody conjugated with a cytotoxic antibiotic (calicheamicin), is approved as a therapeutic option for patients diagnosed with relapsed/refractory CD22-positive B-cell ALL.*

*Materials and methods: In our retrospective, single-center study, we included patients over 18 years of age, diagnosed between 2020–2025 with relapsed/refractory (R/R) CD22-positive B-cell ALL, treated with inotuzumab ozogamicin at the Hematology Clinic of Fundeni Clinical Institute. All relapse samples were analyzed by immunophenotyping to identify the presence of CD22 antigen on the surface of lymphoblasts. Demographic and molecular characteristics of the patients, number of prior therapy lines, and number of Inotuzumab cycles administered were evaluated. We assessed the complete remission rate, measurable residual disease (MRD) status, percentage of patients who underwent allogeneic HSCT, associated toxicities, and 2-year overall survival. Toxicity grade was evaluated according to CTCAE v4.0. Overall survival (OS) was defined as the time interval from the initiation of INO treatment to death from any cause.*

*Results: A total of 26 adult patients were included, with a median age at INO initiation of 46.5 years (range 18–85), of whom 50% were male. The cohort had a median follow-up of 1.5 years. A proportion of 42% (n=11/26) of patients had received 3 prior lines of therapy, and 26.9% (n=7/26) had been treated with blinatumomab. The median number of INO cycles administered was 2 (range 1–6). The overall complete remission rate (CR/CRi) after  $\leq 2$  cycles was approximately 60%, of which 40% achieved MRD negativity. In 26% of patients (n=7/26), the obtained response was consolidated with allogeneic hematopoietic stem cell transplantation. The 2-year overall survival rate was 42% (95% CI). During INO treatment, adverse events of any grade were recorded in 85% of patients. Most non-hematologic toxicities were hepatic, with one patient permanently discontinuing treatment after the first dose due to acute liver failure. Grade 3–4 neutropenia and thrombocytopenia were the most frequent hematologic toxicities.*

*Conclusions: The results obtained in this analysis support the literature data regarding the efficacy of inotuzumab ozogamicin in patients with R/R ALL. INO can be used as a bridging therapy to allogeneic stem cell transplantation, leading to improved overall survival.*

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# Classic Mantle Cell Lymphoma with Early Orbital Relapse - The Importance of Stem Cell Autotransplant (ASCT)

Georgiana Ene<sup>1</sup>, Ana-Maria Ilinescu<sup>1</sup>, Luminița Ocroteală<sup>2</sup>, Gabriela Diana Cantor<sup>1,2</sup>,  
Daiana Tunaru<sup>1</sup>, Fl. Nitu<sup>1</sup>, H. Bumbea<sup>1</sup>

*Purpose: Mantle cell lymphoma (MCL) is a rare malignant entity with aggressive behavior and variable prognosis comprising about 6-8 % of the total non-Hodgkins lymphomas. The classical variant is the most frequent form of histological presentation characterized through a rapid evolution and a high rate of relapse after the initial treatment. ASCT represents a standard therapeutical first line option for the eligible patients making a significant contribution to progression free survival and overall survival rates.*

*Materials and methods: This paper aims to outline the role of ASCT in the therapeutical strategy of classic MCL, through correlation of the data found in literature and a particular clinical case with extra lymphatic relapse – left orbital region- detected during the final clearance for ASCT.*

*Results: The paper outlines the clinical, biological, imagistic and therapeutic data of a patient diagnosed with classic MCL, that had early relapse at the left orbital level, underwent stem cell collection followed by ASCT. The post transplant evolution is analyzed in the context of recent literature data regarding response rates, OS, and prognosis in MCL.*

*Conclusions: This clinical case outlines the particularities of extra lymphatic relapse, favorable response to salvage treatment and the crucial role of ASCT in achieving long term remission. There are discussed data from comparative studies regarding the benefits of ASCT in patient with classical MCL.*

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# Autologous Stem Cell Transplantation in the Era of Immunotherapy: DVTD Versus VCD Induction in Newly Diagnosed Multiple Myeloma

Diana-Marina Fortoes<sup>2</sup>, Elena Nicorici<sup>2</sup>, I. Antohe<sup>1,2</sup>, Elena Dolachi-Pelin<sup>2</sup>, Roxana Dumitru<sup>2</sup>, C. Dănilă<sup>1,2</sup>, Angela Dăscălescu<sup>1,2</sup>

*Background:* Autologous stem cell transplantation (ASCT) remains a cornerstone in multiple myeloma (MM), although daratumumab-based quadruplets have improved depth of response compared with conventional triplets. Direct comparisons between DVTD and VCD in the transplant setting are lacking. Prognostic assessment by the Revised International Staging System (R-ISS) is limited, and additional biomarkers such as the Endothelial Activation and Stress Index (EASIX) may refine risk stratification.

*Methods:* We retrospectively analyzed 99 MM patients  $\leq 70$  years undergoing ASCT between 2017–2023. Median follow-up was 32 months. R-ISS distribution was I (30%), II (64%), and III (6%); 7% harboured high-risk cytogenetics. Induction therapy consisted of DVTD ( $n=37$ ) or VCD ( $n=62$ ); 18 patients in the DVTD group received consolidation. Lenalidomide maintenance was administered to 65%. Outcomes included response rates, progression-free survival (PFS), time to relapse, time to next treatment (TTNT), overall survival (OS), and correlation of EASIX at diagnosis with OS.

*Results:* Complete response (CR) rates were significantly higher with DVTD compared with VCD, both pre-ASCT (57% vs. 24%,  $p=0.001$ ) and post-ASCT (84% vs. 48%,  $p=0.001$ ). Median PFS for the cohort was 63 months (95% CI 44.6–81.4), and TTNT was 23 months. Relapse occurred in 31% of patients, including 8% during maintenance. At a median follow-up of 93 months, median OS was not reached; mean OS was 83 months (95% CI 76–90) with 75% 5-year survival. Overall, 18% of patients died, mainly from infections and relapse.

*Conclusion:* DVTD demonstrated superior response rates compared with VCD and sustained PFS benefit post-ASCT. ASCT remains integral in the era of immunotherapy, while EASIX at diagnosis may provide additional prognostic information.

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# Oxidative Stress – Chronic Inflammation Associations in Primary Myelofibrosis

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Amelia Maria Găman<sup>6,7</sup>, Carmen Cristina Diaconu<sup>1</sup>**

*Aim: Oxidative stress (OS) and low-grade chronic inflammation (LGCI) are key elements in the pathogenesis and leukemic transformation of primary myelofibrosis (PMF). The aim of our study was to investigate the presence of associations between OS and LGCI in PMF.*

*Methods: OS was evaluated by the measurement of the total antioxidant capacity (TAC) by spectrophotometry using plasma samples. LGCI was assessed by deriving several inflammatory markers from the complete blood count (CBC) (neutrophils/lymphocytes, platelets/lymphocytes, monocytes/lymphocytes, lymphocytes/monocytes ratios).*

*Results: PMF patients registered higher TAC and CBC-derived inflammatory markers values versus controls. We detected correlations between OS and CBC-derived LGCI markers in subjects with PMF.*

*Conclusions: There are elevated levels of TAC and inflammatory markers in PMF, as well as associations between these parameters, highlighting an increased grade of myeloproliferation.*

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# Impact of Pregnancy and the Postnatal Period on the Clinical Course and Therapeutic Response in Hodgkin Lymphoma: A Retrospective Comparative Study

**Florentina Adriana Gauianu<sup>1,2</sup>, Oana Diana Preda<sup>1,2</sup>, Sorina Nicoleta Bădeliță<sup>2</sup>, Sînziana Barbu<sup>1,2</sup>, Mihaela Lazaroiu<sup>3</sup>, Mihaela Gaman<sup>1,4</sup>, Loredana Cirlan<sup>2</sup>, Andreea Parpala<sup>2</sup>, T. Lascar<sup>2</sup>, Bianca Tarau<sup>2</sup>, Camelia Dobrea<sup>1,2</sup>, Iulia Ursuleac<sup>1,2</sup>, D. Coriu<sup>1,2</sup>**

*Hodgkin lymphoma (HL) occurs in approximately 8 cases per 100,000 pregnancies, ranking among the most frequent malignant hematologic disorders associated with pregnancy. Data regarding the impact of pregnancy and the postpartum period on HL prognosis remain limited. The aim of this study was to analyze the clinical and histopathological characteristics, as well as therapeutic outcomes, in patients diagnosed during pregnancy or within the first postpartum year, compared with patients diagnosed outside of pregnancy.*

*The present research is a retrospective, multicenter study including 13 patients diagnosed with HL between 2017 and 2025. Data were collected on age at diagnosis, presenting symptoms, lymph node involvement, disease stage, histological subtype, and timing of diagnosis (pregnancy trimester or postpartum). Overall survival (OS) and progression-free survival (PFS) were assessed using the Kaplan–Meier method. Comparisons with non-pregnant patients were performed through 1:1 matching on major prognostic variables.*

*The distribution of stages and histological subtypes was comparable between groups. Treatment responses and survival outcomes showed no significant differences. However, patients diagnosed during pregnancy or in the postpartum period demonstrated a higher risk of infectious complications, which were generally manageable under constant supervision.*

*A diagnosis of HL during pregnancy or postpartum does not significantly alter disease evolution compared with patients diagnosed outside of pregnancy, although the increased risk of infectious complications requires rigorous monitoring. Study limitations include the small cohort size and relatively short follow-up duration. Larger, multicenter studies are needed to validate these findings.*

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# Evaluation and Prediction of Coagulation Status in Amyloidosis

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*Amyloidosis is a heterogeneous disorder characterized by extracellular deposition of insoluble fibrillar proteins, often associated with coagulation abnormalities and an increased risk of thrombotic events. The relationship between systemic inflammation, hemostatic activation, and thrombotic risk in amyloidosis remains poorly understood. We prospectively analyzed 61 patients diagnosed with amyloidosis to assess coagulological status and thrombotic risk. Sixteen patients (26.2%) had documented thrombotic events. Plasma samples were subjected to global hemostasis tests, prothrombin time (PT), activated cephalin time (ACT), fibrinogen, D-dimers, specialized hemostasis tests, thromboelastography (TEG), thrombin generation time (TGT), and factor X activity assay, as well as inflammatory markers. Serum levels of kappa and lambda light chains were also determined, and organ involvement was assessed: cardiac (n=35), hepatic (n=18), and renal (n=30). Logistic regression analysis was used to identify independent predictors of thrombosis and assess the impact of systemic inflammation on hemostasis. Multivariate analysis showed that systemic inflammation does not explain the occurrence of thrombosis. TEG parameters were significantly correlated with inflammatory markers ( $p=0.014$ ), suggesting that inflammation interferes with the viscoelastic assessment of coagulation. In contrast, TGT did not correlate with inflammation ( $p>0.05$ ) but showed a significant association with thrombotic events ( $p=0.0175$ ). TGT results were independent of the treatment instituted ( $p>0.05$ ) and of the assessment of thrombotic risk at the time of diagnosis ( $p>0.05$ ). Standard coagulation tests (PT, TCA, fibrinogen, D-dimers) and factor X levels did not predict thrombosis. In patients with amyloidosis, the thrombin generation time proves to be the most reliable tool for assessing thrombotic risk, being unaffected by inflammation or treatment and significantly correlating with thrombosis. In contrast, TEG is strongly affected by systemic inflammation and may mislead the prothrombotic state. Integrating TGT into the routine evaluation of these patients may optimize risk stratification and guide decisions regarding prophylaxis and anticoagulant therapy.*

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# **FLT3 Positive Acute Myeloid Leukemia - Triple Therapy as an Option for Patients with Refractory/Relapsed Disease - Unicentric Experience**

**Roxana Hirjan, Dana Frângu, Andreea Andrunache, B. Ionescu, Aurelia Tatic, Camelia Stancioaica, Alexandra Ghiaur, Mihaela Cîrstea, D. Coriu**

*Treatment with Gilteritinib in monotherapy for patients with relapsed/refractory acute myeloid leukemia FLT3 positive has become a standard therapy, but the ADMIRAL study has reported a rate of complete remission of only 34% versus 15.3% in salvage therapy. Off label association of BCL2 inhibitor, Venetoclax and hypomethylating agents like Azacitidine can be a therapeutic option for refractory patients with acute myeloid leukemia FLT3 positive.*

*During March 2022 - September 2025 in Fundeni Clinical Institute 24 patients with refractory/relapsed acute myeloid leukemia were treated with Gilteritinib in monotherapy and 30% of these patients were treated with triple therapy. Out of 30%, half of them obtained a complete response and could undergo allogeneic stem cell transplantation. In this study population the most frequent toxicity was hematological.*

*This type of triple therapy is not reimbursed in Romania at this moment, in this setting, but it is widely used as a bridge to allogeneic stem cell transplantation.*

Fundeni Clinical Institute, Bucharest, Romania

# Severe Mast Cell Degranulation, Persistent Thrombocytopenia, and Viral Reactivation after Autologous Stem Cell Transplantation in Mantle Cell Lymphoma

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*Purpose:* Autologous stem cell transplantation (ASCT) is a standard consolidation strategy in mantle cell lymphoma (MCL), generally associated with predictable toxicities. However, immediate hypersensitivity reactions and persistent single-lineage cytopenias are rare.

*Materials and methods:* We report the case of a 49-year-old woman with MCL in partial remission after initial therapy, who underwent ASCT following a TEAM conditioning regimen. Immediately after the first infusion of autologous stem cells, the patient developed severe hypotension, hypoxemia, and cardiac arrest, requiring prompt resuscitation and intensive supportive care. Subsequent laboratory testing, has proven the cause as mastocystig degranulation. The remaining stem cell graft, was later administered. Hematopoietic recovery was achieved for the granulocytic and erythroid lineages; however, the patient developed persistent thrombocytopenia. The differential diagnosis included lineage-specific graft failure versus virus-related thrombocytopenia. PCR testing confirmed concomitant reactivation of cytomegalovirus (CMV) and human herpesvirus-6 (HHV-6), requiring targeted antiviral therapy.

*Results:* This case highlights an unusual constellation of complications after ASCT in MCL: anaphylactic shock during stem cell infusion, incomplete unilineage engraftment, and opportunistic viral reactivation. Potential mechanisms include hypersensitivity to DMSO, disruption of the bone marrow microenvironment impairing megakaryopoiesis, and profound T-cell immunosuppression. Awareness of these rare events is crucial for timely recognition and tailored management.

*Conclusions:* Severe mast cell degranulation during stem cell infusion and selective megakaryocytic graft failure are rare but clinically significant events. Careful infusion monitoring and early viral surveillance may improve the management of such cases.

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# Treatment Patterns and Real-World Outcomes in Multiple Myeloma: Experience of the Hematology Department II, Colentina Clinical Hospital, Bucharest

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*Background:* Multiple myeloma (MM) is a heterogeneous disease, and real-world data are essential to complement clinical trial findings.

*Methods:* We analyzed all patients treated for MM in Hematology Department II, Colentina Clinical Hospital, between 2020–2025. Baseline characteristics, transplant eligibility, treatment patterns, and survival outcomes were evaluated.

*Results:* A total of 37 patients were included; median age was 70 years (IQR 64–76), 51% male. ISS stage at diagnosis: I 22%, II 22%, III 57%. Thirteen patients (35%) were transplant-eligible, but only 24% of the cohort underwent ASCT. First-line regimens included DaraRd (27%), CyBorD (22%), VRd-lite (19%), DaraVRd (11%), DarVTd (8%), while VelDex, VRd, and LenDex each accounted for <6%. The overall response rate was 89%, with 70% achieving  $\geq$ VGPR. PFS was 90% at 1 year and 81% at 2 years. OS remains immature, with only 4 deaths recorded.

*Conclusions:* This real-world cohort analyzed MM patients treated over the past five years, with transplant-ineligible patients representing the majority. Transplant-eligible patients received modern daratumumab- and proteasome inhibitor-based combinations as first-line therapy, and most of them underwent ASCT. Outcomes in routine practice are comparable to those reported in clinical trials, though longer follow-up and expansion of the database are needed for robust estimates.

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# Hereditary Transthyretin Amyloidosis (hATTR) - A Clinical Case and Insights from Romanian Experience

Andreea Jercan, Sorina Bădeliță, D. Coriu

*Hereditary Transthyretin Amyloidosis (hATTR) represents a rare, autosomal dominant genetic disorder arising from mutations in the transthyretin (TTR) gene. This condition is characterized by the aberrant folding of TTR protein, resulting in the formation of amyloid fibrils that can deposit in various tissues. This presentation will delve into a clinical case involving a Romanian patient with the Glu54Gln mutation, shedding light on the significant genetic and clinical diversity observed within the Balkan region.*

*To date, more than 130 distinct mutations of the TTR gene have been documented, leading to a wide spectrum of phenotypic expressions. These manifestations can be predominantly neurologic, cardiac, or a combination of both.*

*The Glu54Gln variant, which is particularly prevalent among Romanian patients, is associated with a mixed clinical phenotype that tends to exhibit aggressive disease progression and a notably reduced survival rate. The case in focus involves a 51-year-old female, whose clinical journey began with the insidious onset of progressive neurological symptoms, including bilateral paresthesia and disturbances in gait. This ultimately led to a diagnosis of familial transthyretin amyloidosis following a comprehensive evaluation period lasting nine months.*

*Additionally, this presentation will encompass the epidemiological landscape of hATTR in the Balkans, highlighting the frequency of mutations such as Glu89Gln in Bulgaria and North Macedonia, as well as the late-onset Val30Met variant. Emphasizing the critical nature of early diagnosis, the discussion will outline the importance of timely therapeutic interventions. Treatments, including transthyretin stabilizers now available in Romania, can significantly alter the disease trajectory. This case serves as a poignant reminder of the necessity for heightened awareness and proactive screening for hATTR, especially in non-endemic areas, to facilitate improved patient outcomes through prompt and effective management.*

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# **Integrating Machine Learning with Real-World Evidence to Reveal Tki-Based Care Pathways in Chronic Myeloid Leukemia: Data from 201 Cases in Cluj-Napoca, Romania**

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*Tyrosine-kinase inhibitors (TKIs) have transformed chronic myeloid leukemia (CML) into a highly manageable disease. However, real-world data on treatment-free remission (TFR) in Eastern Europe remain limited. The objective of this study was to assess TFR outcomes and predictors among Romanian CML patients. We conducted a retrospective analysis of 201 adult patients treated at the Cluj-Napoca Hematology Department between 2001 and 2024. Structured clinical data were extracted using a Large Language Model to process discharge summaries and identify treatment history, molecular responses, and TFR-related endpoints. Machine learning models were built to predict TFR potential. At diagnosis, 94.5% of patients were in chronic phase. First-line TKIs included imatinib (53.7%), dasatinib (27.9%), and nilotinib (18.4%). Sustained TFR was achieved by 14 patients (7.0%), with nilotinib accounting for 8 of these cases (57.1%), making it the most effective TFR-enabler. Nilotinib was also linked to six additional TFR-eligible patients and achieved deep molecular response (MR4+) in 43.3% of third-line exposures. Predictive modelling using a Random Forest classifier achieved 85.4% accuracy. The most powerful predictor of TFR success was achieving a deep molecular response (MR4), followed by response timing and molecular stability. Despite a substantial eligible population, TFR remains underused. Nilotinib showed superior performance in both inducing and sustaining deep remissions. These results highlight the importance of optimized molecular monitoring and structured discontinuation protocols to improve TFR outcomes in real-world clinical practice.*

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# Bispecific Antibodies and CAR-T in Refractory DLBCL: Patient Outcomes And Toxicity Profile

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Angela Dăscălescu<sup>1,2</sup>

*Diffuse large B-cell lymphoma (DLBCL) is the most common form of aggressive non-Hodgkin lymphoma in adults. Standard R-CHOP therapy is effective in approximately 70% of cases. Bispecific monoclonal antibodies and CAR-T cell therapy have shown promising results in refractory cases. To date, 7 patients in our clinic have been treated with bispecific antibodies and 5 patients with CAR-T therapy. We present the patient profiles, treatment-related complications, and therapeutic outcomes.*

*Among patients treated with bispecific antibodies (n=7), three (42.8%) achieved a therapeutic response (two complete, one partial). CRS of any grade occurred in five patients (71.4%), including three grade 5 events (all with high EASIX scores), two grade 2 events, and one patient who developed ICANS. Four patients (57.1%) died, three due to grade 5 CRS and one due to disease progression. In the CAR-T cohort (n=5), two patients (40%) responded to treatment, three (60%) were refractory, and CRS occurred in four patients (80%): three grade 2 and one grade 1 events, with no ICANS observed.*

*Novel therapies offer a new chance for patients who are refractory to conventional treatments, with remission rates of approximately 40% in our series. Although toxicity (particularly CRS) remains a challenge, our data confirms the efficacy of BiTEs and CAR-T as well as the utility of the EASIX score for risk stratification, supporting the integration of these therapies into current practice.*

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# Screening for Secondary Cancers in Patients with CLL or SLL: A Key Component of Long-Term Management

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*Introduction: Chronic lymphocytic leukemia (CLL) is associated with an increased risk of secondary malignancies, potentially influenced by impaired immune status and exposure to successive lines of therapy. The aim of this study was to evaluate the incidence and spectrum of secondary neoplasms in a cohort of patients with CLL.*

*Methods: We conducted a retrospective analysis of 160 patients with CLL treated at the Fundeni Clinical Institute. Of these, 53 patients (33%) were treatment-naïve and received either ibrutinib or chemoimmunotherapy, while 107 patients (67%) were treated with ibrutinib for relapsed or progressive CLL. The median follow-up period was 30 months.*

*Results: Secondary cancers were diagnosed in 17 patients (10.62%). The most frequent were non-melanoma skin cancers (n=6), followed by lung, liver, and colorectal cancers (2 cases each). Additionally, one case each of hematologic malignancy, brain tumor, breast cancer, liposarcoma, and laryngeal cancer was identified. More than 90% of these secondary malignancies occurred in patients who had received at least second-line therapy. Notably, 9 patients had a prior history of cancer at therapy initiation, but no progression or recurrence of these malignancies was observed during follow-up.*

*Conclusions: The incidence of secondary cancers in the studied cohort was approximately 10%, with a predominance of non-melanoma skin cancer. The risk was higher in patients exposed to multiple lines of therapy, while prior oncological history did not negatively impact outcomes. These findings highlight the importance of close monitoring of CLL patients, particularly those undergoing successive therapeutic regimens.*

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# Immunomodulatory Impact of Brentuximab Vedotin on Regulatory T Cells in Advanced Hodgkin Lymphoma Patients

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*Objective: Hodgkin lymphoma (HL) is a hematological malignancy of the lymphatic system, classified into classical HL (cHL, ~95% of cases) and nodular lymphocyte-predominant HL (~5%). The tumor microenvironment of cHL is shaped by Hodgkin-Reed Sternberg (HRS) cells through secretion of growth factors, chemokines, and cytokines, creating an immunosuppressive environment that supports tumor growth and survival. T lymphocyte populations (CD4+, CD8+, Tregs) play a key role in this microenvironment. Brentuximab vedotin (BV), an anti-CD30 antibody-drug conjugate, combined with AVD chemotherapy, has become the standard of care in advanced HL; however, its effects on the immune compartment remain insufficiently characterized.*

*Materials and methods: We included 15 patients diagnosed with stage IV cHL, treated with AVD + BV at Fundeni Clinical Institute. Clinical and immunological parameters were assessed at baseline and during therapy. Peripheral blood immunophenotyping was performed by flow cytometry, evaluating total T lymphocytes (CD3+), CD4+ helper T cells, CD8+ cytotoxic T cells, B cells (CD19+), NK cells, and regulatory T cells (CD4+CD25+FOXP3+).*

*Results: The cohort had a median age of 46 years, with nodular sclerosis as the most common histological subtype (60%). Adverse events included peripheral neuropathy (80%, almost half with grade 2) and anemia (26%). Immunologically, we observed a transient decrease in CD3+ T lymphocytes followed by recovery, and a more than threefold increase in Treg populations post-treatment. B cells and NK cells showed increasing trends without statistical significance.*

*Conclusions: Brentuximab vedotin exerts a dual effect in advanced HL: direct cytotoxicity against HRS cells and immunomodulation through remodelling of the T-cell compartment. The observed changes in T-cell populations may contribute to therapeutic efficacy and could serve as potential biomarkers for treatment response and prognosis. These findings support further studies to elucidate the interplay between targeted therapy and immune reconstitution, with possible integration into combined immunotherapeutic strategies.*

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# Forays into Thrombotic Events in Patients with Malignant Lymphomas and Cancer

**V. Musteață**

*Aim: The aim of the study was to identify the diagnosis patterns and assess the results of treatment of thrombotic complications in patients with non-Hodgkin lymphoma (NHL) and breast cancer (BC).*

*Material and Methods: We performed a descriptive, prospective study of cases with stage IIA diffuse large B-cell NHL, stage IVB marginal zone B-cell NHL and stage T2N1M0 BC, who were treated and followed up at the Institute of Oncology. All these patients were the females of 38, 45 and 46 years old, with tumor progression and concomitant diseases: Grade I obesity; Hyperglycemia. The diagnosis was proved by histopathological and immunohistochemical examinations of the biopsied tissues and standard staging procedures, including CT scan.*

*Results: The patient with progression of marginal zone B-cell NHL received CHOP regimen and obtained a partial response. She developed thrombophlebitis of the left shin and underwent the antiplatelet and anticoagulant therapy. The patient with progression of diffuse large B-cell NHL was treated with R-CHOP chemotherapy combined with antiplatelet medication, with partial response, followed by the loco-regional radiotherapy (LRT) on the residual tumor site. The LRT was temporarily stopped due to the development of venous thrombosis signs of the right femur. Duplex sonography proved the diagnosis of the acute grade II phlebothrombosis. D-dimers ranged between 900-1200 ng/mL. All patients responded with the venous recanalization to the daily oral antiplatelet and anticoagulant therapy. The patient continued the LRT and achieved the complete response.*

*Conclusions: The progression of NHL and BC may be associated with thrombotic and thromboembolic complications, especially if emerged with metabolic and vascular disorders. The monitored prophylactic oral antiplatelet and anticoagulant therapy should be administered during the remission induction.*

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# From CAR-T Indication to Procedure Implementation: A Retrospective Analysis of Adult Patients with Refractory/Relapsed Non-Hodgkin Lymphoma at Fundeni Clinical Institute

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*Background:* Chimeric Antigen Receptor T-cell (CAR-T) therapy has revolutionized the treatment of relapsed/refractory B-cell malignancies. In Romania, CAR-T is currently approved for diffuse large B-cell lymphoma (DLBCL) in patients unresponsive to conventional treatments and for B-cell acute lymphoblastic leukemia (B-ALL) in patients up to 25 years of age with refractory/relapsed disease.

*Objectives:* This retrospective study aims to analyze the clinical course of patients referred for CAR-T therapy, from the time of indication to the actual administration of treatment, with a focus on patient selection, therapeutic history, bridging strategy, and post-infusion clinical outcomes.

*Methods:* A total of 30 adult patients diagnosed with refractory/relapsed Non-Hodgkin's Lymphoma were retrospectively analyzed. These patients were selected by the National CAR-T Commission and were enrolled for the procedure between 2022 and 2025 at the Fundeni Clinical Institute. Data were collected regarding previous therapeutic lines, histological subtype (double-expressor, high-grade, transformed), bridging therapies, and the response to these treatments, as well as complications related to CAR-T administration and treatment response parameters (remission, relapse).

*Results:* All patients exhibited a high number of previous therapeutic lines, associated with cumulative hematologic toxicity. Three patients were enrolled but were unable to undergo the procedure due to rapid disease progression and deterioration of their general condition, which led to death shortly thereafter. In patients who received CAR-T therapy, common complications included cytokine release syndrome (CRS) grade 3–4, neurotoxicity associated with effector cells (ICANS), prolonged aplasia, and infections of varying severity. Prolonged hematologic aplasia was correlated with an increased risk of infections, likely multifactorial—determined by the cumulative toxicity of previous treatments and secondary immune remodeling induced by CAR-T. The bridging strategy had a significant impact on post-procedural response, being notably influenced by the presence or absence of bulky disease.

*Conclusion:* This analysis highlights the importance of early identification of eligible patients, prioritizing cellular collection in patients with primary refractory disease, without waiting for a response to second-line therapy, and the careful selection of bridging therapy. Optimizing these steps could contribute to reducing hospitalization duration, lowering the incidence of complications, and improving overall survival rates among patients treated with CAR-T cells.

*Keywords:* CAR-T therapy, non-Hodgkin lymphoma, bridging therapy, cytokine release syndrome, ICANS, aplasia, real-world data, Romania

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# Multiple Myeloma in the Young Patient: Between Rarity and Reality

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*Purpose: Although classically perceived as a "disease of the elderly", the incidence of multiple myeloma in young patients has increased by 2-3% annually over the past two decades. This increase can be partially attributed to improved diagnostic techniques and clinical awareness.*

*Material and method: Young patients often present with less advanced disease, frequently the light chain subtype, and most often less aggressive forms (ISS stage I). Overall survival is often better than in the elderly, due to better tolerance to intensive treatments, fewer comorbidities, and deeper responses after autologous transplantation.*

*Results: Multiple myeloma in young patients represents a subpopulation with distinct characteristics and relatively favorable outcomes, but is understudied. Multicenter studies with larger populations using R-ISS and modern therapies are needed to improve the understanding and treatment of this category. Also, long-term management and extended survival deserve special attention, given the impact on the personal and professional lives of young patients.*

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# Cytokine Release Syndrome During Bispecific Antibody Therapy – A Single-Center Experience

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*Objective:* Cytokine release syndrome (CRS) is the main adverse event associated with bispecific antibody therapy for malignant hematologic disorders. The identification of potential predictive factors available at treatment initiation could optimize patient monitoring.

*Materials and methods:* This study is a retrospective, single-center study including 9 patients who received bispecific antibody therapy between 2023 and 2025. For each patient, demographic data, prior lines of therapy, and baseline laboratory parameters at treatment initiation were collected, along with information regarding the occurrence of CRS and survival outcomes. Statistical analysis was performed using SPSS v26.

*Results:* CRS had an incidence of 44.4% (4 cases), all grade 1–2, with no severe events, related neurologic toxicity, or serious infections observed. Baseline C-reactive protein (CRP) levels were significantly higher in patients who later developed CRS. Serum albumin levels showed a significant negative correlation with the number of prior therapy lines, suggesting a relationship between cumulative therapeutic exposure and the patient's functional status. No other significant associations were found between other variables and CRS occurrence. Patient survival rates were not influenced by the presence of CRS.

*Conclusions:* The findings of this study are in line with those reported in the existing literature. Larger studies are needed to clarify risk stratification in the context of these novel therapies.

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# Prognostic Factors in Polycythemia Vera

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*Objectives: To identify clinical, biological and therapeutic factors associated with thrombosis in PV patients.*

*Methods: We conducted a retrospective, single-center study of 89 JAK+ PV patients diagnosed and treated between January 2015-August 2025 at the Hematology Department of the "Prof. Dr. Ion Chiricuță" Oncology Institute Cluj-Napoca. Demographic, clinical, treatment related and laboratory data (erythrocytes, hemoglobin, hematocrit, RDW, leukocytes, platelets, ferritin) were analyzed. Statistical evaluation was performed in GraphPad Prism using t-tests, Chi-square tests and logistic regression.*

*Results: The median age at diagnosis was 61,3 years; 50,56% were male. Comorbidities were present in 53,93%, most frequently hypertension (25,84%). Thrombosis occurred in 19 patients (21,3%): 7 pre-diagnosis, 11 post-diagnosis and 1 both pre- and post-diagnosis, with an equal arterial/venous distribution (47,37%). In univariate analysis, patients with thrombosis were older (66,63 vs. 59,91 years;  $p=0,039$ ) and had higher RDW (53,6 vs. 49,17;  $p=0,007$ ). Other factors (comorbidities, treatment) were not significantly associated with thrombosis. Multivariate regression identified RDW as the only independent predictor of thrombotic risk ( $OR=1,75$ ; 95%CI: 1,06–4,29;  $p<0,005$ ). Age and lower hematocrit showed trends ( $OR=1,045$  and  $OR=0,62$ ) without statistical significance.*

*Conclusions: RDW, a simple and affordable hematologic parameter, was independently associated with thrombotic risk in PV and may serve as an additional marker for thrombotic risk stratification.*

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# Relapsed Hodgkin Lymphoma: Insights from the National Registry on Escalated Therapy and Autologous Stem Cell Transplantation

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*Relapsed or refractory Hodgkin lymphoma (R/R HL) remains a therapeutic challenge, although most patients achieve remission after first-line therapy. The current standard for R/R HL consists of salvage chemotherapy followed by intensive conditioning and autologous stem cell transplantation (ASCT), with 3–5 year survival rates of 70–90% in patients who achieve complete remission and PET negativity before ASCT. Poor prognosis is associated with primary refractory disease and early relapse. The introduction of Brentuximab Vedotin (BV) and PD-1 inhibitors (Nivolumab, Pembrolizumab – approved in the USA) has increased response rates and survival, both pre- and post-ASCT, including in patients with early relapse or refractory disease.*

*Following the introduction of these agents, post-ASCT options now include BV, PD-1 inhibitors, allogeneic transplantation, and experimental cellular therapies. Reflecting these advances, national registries show a clear improvement in survival over the past decade, particularly for patients with early post-ASCT relapse due to innovative therapies.*

*In this study, data from the National Hodgkin Lymphoma Registry were analyzed, reflecting clinical reality and experience in routine medical practice. These data were compared with information reported in international registries. The results highlighted the major impact of early diagnosis and rigorous staging on clinical outcomes. Additionally, the importance of selecting therapeutic strategies based on individual risk factors was emphasized; this approach contributes to higher response rates and improved long-term survival. The integration of these real-world data enabled the harmonization of national practices with international standards and optimized therapeutic resource utilization.*

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# Synchronous Multiple Primary Malignancies – Solid and Hematological Malignancy –Literature Data and A Short Case Series

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*Introduction: Synchronous multiple primary malignancies are not uncommon, but the majority of cases are diagnosed consecutively, separated by an interval of several years. Generally, these are considered secondary malignancies, related to prior chemotherapy exposure. Concurrently diagnosed multiple primary malignancies, defined as those occurring simultaneously or within a maximum interval of six months, are rare, with a reported incidence between 0.73% and 11.7%. Cases in which one of the neoplasms is of hematological origin are exceptionally uncommon.*

*Aim: Providing a brief overview and presentation of a short series of cases diagnosed with synchronous neoplasia, one of whom hematological, treated in Hematology Clinic of Craiova, between 2021-2024*

*Material and methods: Data from scientific papers and medical documents from four patients diagnosed with synchronous neoplasia has been collected, after they had signed the informed consent to publishing the cases.*

*Results: Four cases of synchronous malignancies were identified, one of which included a hematological neoplasm. Patients ranged in age from 31 to 64 years, with an equal sex distribution (two male, two female). The combinations of synchronous malignancies were as follows: Hodgkin lymphoma-thyroid papillary carcinoma, metastatic colorectal carcinoma-acute myeloid leukemia, breast cancer-mediastinal primitive DLBCL lymphoma and neuroglioma-high risk myelodysplastic syndrome. Two patients died within eight months following the diagnosis, the other two are alive at the time of reporting.*

*Conclusion: Although rare, synchronous neoplasia, are extremely severe and are associated with significant diagnostic and therapeutic challenges. The tumor board, including a pathologist, an imaging specialist, a genetician, an oncologist and a hematologist is essential for individualized case management. There is no standardised treatment, however treating the most aggressive neoplasia first is commonly recommended.*

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# Challenges in NGS Diagnosis and Clinical Practice – Where Did the Good Prognosis Go?

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*Background: Mutations in CEBPA are recognized as prognostically favorable in AML, particularly when biallelic and involving the basic leucine zipper (bZIP) domain. However, the prognostic relevance of monoallelic CEBPA mutations located outside the bZIP domain remains unclear. We report two young adults with de novo AML and monoallelic CEBPA frameshift mutations outside the bZIP region, aiming to explore their mutational landscape and divergent clinical evolution.*

*Methods: At diagnosis, targeted next-generation sequencing (NGS) with full CEBPA gene coverage and a myeloid malignancy panel was performed. Cytogenetic analysis and multiparametric flow cytometry were used for disease classification. Clinical decisions followed current ELN guidelines, and measurable residual disease (MRD) was monitored throughout treatment.*

*Results: Patient A harboured a CEBPA p.G101Afs\*59 mutation (VAF 47.85%) and a cooccurring GATA2 p.R362Q (VAF 36.94%). She received induction chemotherapy with cytarabine and anthracycline, followed by two allogeneic hematopoietic stem cell transplants. Despite initial remission, she relapsed twice and remains under active care. Patient B carried a CEBPA p.H24Afs\*84 mutation (VAF 28.16%), GATA2 p.N317S (VAF 20.45%), and FLT3-ITD. He was treated with cytarabine, anthracycline, and midostaurin, followed by salvage FLAG chemotherapy. A haploidentical transplant is currently being planned. No additional CEBPA mutations were identified in either case. Both frameshift variants were located outside the bZIP domain. Their distinct clinical trajectories and adverse mutational partners challenge the current classification of these mutations as favorable.*

*Conclusions: These findings highlight the limitations of current risk stratification frameworks that prioritize bZIP localization and biallelic status in CEBPA-mutated AML. Monoallelic non-bZIP CEBPA mutations, particularly when accompanied by adverse co-mutations such as GATA2 or FLT3-ITD, may not confer a favorable prognosis. Comprehensive genomic assessment and context-aware variant interpretation are essential for accurate risk classification and treatment guidance in AML.*

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# Hereditary Spherocytosis and Primary Myelofibrosis: Coincidence or Shared Pathogenic Mechanism?

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*Purpose: The simultaneous diagnosis of hereditary spherocytosis and primary myelofibrosis is exceptionally rare. Both conditions share common clinical features, such as anemia and splenomegaly, and require an extensive range of paraclinical investigations for differential diagnosis. Although they originate from distinct cells and have different pathogenic mechanisms, a potential link between the two hematological disorders cannot be excluded.*

*Materials and methods: We report the case of a 57-year-old patient referred to our clinic for evaluation of an anemic syndrome that had developed two years earlier, during which splenomegaly was also detected. The diagnostic work-up included complete blood count with reticulocyte count, peripheral blood smear, hemolysis markers, Coombs tests, osmotic fragility testing, molecular assays for chronic myeloproliferative neoplasms, bone marrow biopsy, and abdominal ultrasonography.*

*Results: Initial laboratory findings supported a diagnosis of mild hereditary spherocytosis. However, the presence of thrombocytosis and the disproportion between splenomegaly and hemolysis severity prompted further investigations, leading to the additional diagnosis of CALR-positive primary myelofibrosis. Specific treatment for both conditions was initiated, with regular follow-up to monitor disease progression.*

*Conclusions: Given the rarity of this association and the scarcity of data in the literature, this case may provide a basis for future studies exploring potential shared pathogenic mechanisms.*

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# Late Side Effects of Tyrosine Kinase Inhibitors in the Treatment of Chronic Myeloid Leukemia. Single-Center Experience

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*Thyrosine kinase inhibitors (TKIs) are the standard of care in chronic myeloid leukemia (CML). According to data provided by European Leukemia Net, one third of patients will change at least once the type of TKI because of intolerance or inefficacy. Side effects can occur within the first year of starting treatment or later. The study aims to evaluate the types of late adverse reactions, their connection to patient risk factors, comorbidities, but also hematologic disease status at the time of the adverse reaction.*

*Material and methods: A retrospective, single-center study, using information obtained from "Hipocrate" app for patients diagnosed with chronic myeloid leukemia (CML), treated and followed-up in Fundeni Hematology Clinic between 2011-2025. Clinical-epidemiological data, types of TKIs, types of late adverse reactions, circumstances of occurrence, hematological disease status were analyzed. The information was adapted in EXCEL format, data processing was performed with SPSS version 31.0.0.0.*

*Results: 36 patients were identified with late adverse reactions (more than 1 year after the start of TKI). These were: metabolic (4), cardiovascular (9), thyroid involvement (4), skin involvement (8), rectocolitis (2); second malignancy occurred in 11 patients. The median age at diagnosis of CML was 48.69 years. The median range from TKI initiation to adverse event (AE) was 4.3 years. CML status at late AE onset was: MMR (13), MR4 (8), MR4.5 (3) and 3 patients were in treatment-free remission (TFR). 1 patient had at the time of the second neoplasm diagnosis progressive disease with T315I mutation.*

*Conclusions: In our study, AE occurred more frequently in females (20 cases). Cardiovascular events (9 patients) ranked first. The second neoplasm occurred in 11 patients. Risk factors associated with neoplasia were identified in 7 patients. The median period between the initiation of the first TKI and the occurrence of neoplasia was 7.9 years. The problem of second malignancy in patients treated with TKI is mentioned in various case reports, but large cohort studies are needed to establish direct causality.*

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# Monoclonal Gammopathy of Renal Significance: From MGUS to Kidney Damage – Experience of Fundeni Clinical Institute

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*Introduction: Monoclonal gammopathy of renal significance (MGRS) comprises renal lesions caused by nephrotoxic monoclonal immunoglobulins secreted by small plasma cell or B-cell clones not meeting criteria for multiple myeloma, lymphoma, or AL amyloidosis.*

*Methods: We retrospectively analyzed patients diagnosed with MGUS between January 2015 and July 2025 at Fundeni Clinical Institute. Of 326 cases, 33 (10%) were classified as MGRS, defined as biopsy-proven renal involvement or, when biopsy was not feasible, by strong clinical suspicion. Clinical, laboratory, and histopathological data were collected.*

*Results: Median age was 58 years (47–76), with female predominance (61%). Monoclonal proteins were light chains-only in 36.4%, IgG in 33.3%, IgM in 27.3%, and IgA in 3.0%;  $\kappa/\lambda$  was 76%/24%. Renal pathology was heterogeneous, most commonly light chain deposition disease (LCDD, 24.2%), proliferative glomerulonephritis with monoclonal deposits (PGNMID, 12.1%), and light chain proximal tubulopathy (LCPT, 12.1%). Podocytopathies were also observed, including minimal change disease and focal segmental glomerulosclerosis. 6.1% were not biopsied. Extra-renal involvement included neuropathy (n=6) and skin manifestations (n=2). At baseline, median creatinine was 2.05 mg/dl, eGFR 31 ml/min/1.73 m<sup>2</sup>, and proteinuria 3.2 g/24h. Most patients (87%) received clone-directed therapy, predominantly bortezomib-based. Overall response rate ( $\geq$ VGPR) occurred in ~60% and correlated with renal improvement, while non-responders progressed, some to dialysis.*

*Conclusions: MGRS was identified in 10% of MGUS patients and presented with advanced renal impairment. Despite histopathological heterogeneity, clone-directed therapy achieved major hematologic responses in 60% of cases, translating into renal benefit. Early recognition and multidisciplinary management are crucial to prevent irreversible kidney damage.*

*Keywords: monoclonal gammopathy of renal significance, MGRS, plasma cell dyscrasia, light chain deposition disease, proliferative glomerulonephritis with monoclonal deposits, podocytopathies*

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# Correlation of Donor Characteristics with Factor V and Factor VIII Levels

**Paula Badea, Luminița Rusen**

*The purpose of the study: Coagulation factors are essential for maintaining normal hemostasis. FVIII acts as a critical cofactor, and low levels of it may lead to excessive bleeding. The aim of this study is to determine the association between donor characteristics, such as age, sex, and blood type, and FV and FVIII levels.*

*Material and method: Donor screening was performed according to the EDQM donor selection guidelines. The evaluation of coagulation factors V and VIII was performed using a Sysmex CS 2500 automated analyzer. Statistical analysis was performed using the Mann-Whitney U test and the Kruskal-Wallis test.*

*Results: The study included 246 eligible participants, all of whom were voluntary blood donors, aged 18 to 57 years, between November 2023 and May 2024. It was found that, for both FV and FVIII, the percentage of donors with abnormal levels of coagulation factors ( $<70\%$ ) was 8.53% each. Specifically, 16 donors had  $FV < 70\%$ , 16 donors had  $FVIII < 70\%$ , and 5 donors had both FV and FVIII below the normal limit.*

*By processing the data, multiple statistically significant results were recorded. Thus, following the analysis between donors of group 0(I) and those of non-0(I) group, higher levels of FV ( $p=0.008$ ) and FVIII ( $p<0.0001$ ) were highlighted in donors of group non-0(I). Regarding the age of the donors, it is worth noting the increase in both FV ( $p=0.03$ ) and FVIII ( $p<0.0001$ ) with advancing age. Finally, sex did not prove to be a statistically significant criterion for the levels of FV ( $p=0.42$ ) and FVIII ( $p=0.09$ ).*

*Conclusion: This study demonstrated a significant correlation between donor characteristics, such as blood type and age, with levels of coagulation factors VIII and V.*

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# **Comparative Analysis of Some Donor Eligibility Criteria: NBTS and Western Transfusion Systems**

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**A.H. Bugner**

*In order to investigate the opportunity of updating some of the blood donor eligibility criteria applied in the National Blood Transfusion System (NBTS) of Romania, we reviewed the eligibility criteria applied in countries such as Italy, the United Kingdom, and the United States of America.*

*Differences can be observed regarding the eligibility of donors over 60 years of age, those with psoriasis, vitiligo, diabetes, asthma, vision impairment, Hashimoto's thyroiditis, schizophrenia, those who have a recent tattoo or piercing or have undergone acupuncture, those who have suffered from hepatitis A, gonorrhea, tuberculosis, female donors who have recently given birth, or those who are on their menstrual cycle.*

*In conclusion, an update of the eligibility criteria would be welcome, along with efforts to ensure the uniform application of the new criteria across the entire NBTS.*

Foundation for Non-Remunerated Blood Donors

# Selection of Compatible Platelet Concentrates for a Patient with Acute Myeloid Leukemia Case Presentation

Ruxandra Caisan<sup>1</sup>, Lorena Ulea<sup>1</sup>, Ana Moise<sup>1</sup>, Ioana Gingu<sup>1</sup>, Geanina Ofiteru<sup>2</sup>,  
Monica Dutescu<sup>1</sup>

*Introduction:* Platelet concentrate treatment is a substitute treatment for patients with neoplastic diseases with severe thrombocytopenia occurring after the administration of induction courses. Not in all cases, platelet transfusion is followed by an increase in the platelet count, sometimes being ineffective.

*Purpose:* Presentation of a polytransfused patient with acute myeloid leukemia with thrombocytopenia below 10,000/mm<sup>3</sup>, post-induction course status in order to obtain complete remission, who presented severe thrombocytopenia below 1,000/mm<sup>3</sup>, after the administration of 2 irradiated TCU. Investigation of the cause of the ineffectiveness of the administered platelets was requested, in order to select compatible platelet concentrates for the patient.

*Material and method:* Blood samples were collected to detect anti-HLA and subsequently anti-HPA immunization. The testing protocol for anti-HLA class I antibodies by the LUMINEX technique used specific kits. Platelet concentrates were carefully selected by the CDC direct compatibility test.

*Results:* Screening/identification of anti-HLA class I antibodies revealed anti-HLA B and anti-HLA C specificities with fluorescence parameters ranging from 30193-2416. The compatibility between the patient's serum and T lymphocytes from 38 platelet donors was tested. The cytotoxicity test was negative in 36.8% of cases and these platelet concentrates were administered to the patient. Positive results were obtained in 63.2%, which was a contraindication to the administration of these preparations.

*Conclusions:* Detection of patient immunization in the HLA and HPA system and the administration of compatible platelets are considerations for the rational use of labile blood products.

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<sup>2</sup> Clinical Hospital Colentina Bucharest, Romania

# **The Impact of the Increase in the Value of the Meal Tickets on Blood Donors from the CTS Bucharest – 2023-2024**

**Cirstea Adela**

*The goal: Evaluating the number of blood donors with the increase in the value of the meal tickets.*

*Material and method: The number of blood donors present in CTS Bucharest from the years 2023-2024 was comparatively analyzed. The result: the significant increase in the number of blood donors as a result of the increase in the value of the meal voucher.*

*Conclusions: The increase in the value of the voucher (meal ticket) has led to a significant increase in the number of blood donors within CTS Bucharest, an increase in the need for used materials, an increase in the waiting time, a decrease in the duration of the medical consultation, unsure filling of the questionnaire (donors no longer answer the questionnaire with the same accuracy or sincerity, resulting in a decrease in the certainty of the safety of the blood donation in many cases), an increase in the number post-blood donation incidents.*

*Overall, the final consequence being the increase in the amount of blood distributed to hospitals, the increase in the life expectancy of patients in hospitals*

Bucharest Blood Transfusion Center, Romania

# Digitalization – A Necessity for Risks Reduction in a Blood Transfusion Center

**Larisa Corobcean**

*Purpose: The paper highlights the impact of the lack of digitalization on the safety and efficiency of activities carried out in a blood transfusion center, presenting successful international models and proposals for the implementation of IT solutions that reduce professional and clinical risks.*

*Material: The risks associated with the use of paper-based documentation, the lack of digital traceability of blood, the overwork of medical staff and the risks of human error are analyzed. Examples from Croatia, Italy, Poland and Scandinavia are presented, where digitalization has improved traceability, transfusion safety and decision-making support for doctors.*

*Method: The paper uses a comparative and descriptive method to analyze the differences between the current Romanian model and practices in other European systems. The benefits of technologies such as artificial intelligence, digital traceability and telemedicine in the activity of transfusion centers are identified.*

*Result: The paper demonstrates that digitalization can significantly reduce the risks of error, streamline medical procedures and protect personnel in transfusion centers. International examples provide a concrete basis for the development of a modern, interoperable and secure national system.*

*Conclusion: In the current context, the digitalization of transfusion centers in Romania is an urgent and strategic measure. The implementation of integrated IT systems, inspired by validated international models, can contribute decisively to reducing risks, protecting patients and supporting doctors in making the right clinical decisions. A firm institutional commitment to investment, training and interdisciplinary collaboration is essential.*

Bucharest Blood Transfusion Center, Romania

# Study on the Presence of Kell Antigen in Blood Donors from the Galati Blood Transfusion Center

**Beatrice Adela Cristian, Nicola Beatrice Cristian**

*Research objectives: Determination of the prevalence of positive Kell antigen in blood donors from the Galati Regional Blood Transfusion Center (CRTS) during the period 1.03.2024- 28.02.2025.*

*Comparison of the presence of Kell antigen according to sex, blood group, age.*

*Evaluation of the clinical and transfusion implications of the results obtained.*

*Research methodology:*

*Type of research: descriptive, cross-sectional.*

*Study population: all blood donors registered at CRTS Galati between March 1, 2024 and February 28, 2025.*

*Data collection methods:*

*Donor forms completed at CRTS Galati;*

*Serological results from the laboratory;*

*Demographic data (sex, age, blood group).*

*Results:*

*Most donors are Kell negative, consistent with data from the specialized literature.*

*The predominance of male donors is clear in almost every month.*

*The Kell antigen is most frequently present in the 40-59 year old age group.*

*The distribution by blood groups shows a predominance of positive Kell antigen in group A+ (34.29%) and O+ (29.71%). Group AB- did not register any Kell positive donors*

*Conclusions: This study contributes to a better understanding of the immunological profile of blood donors in Galati county, providing relevant data for local transfusion practice.*

Galati Regional Blood Transfusion Center, Romania  
Faculty of Medicine and Pharmacy Galati, Romania

# Liberation from Quarantine: Let's Get into the Criticality of the Activity, Beyond Words

**Alina Mirella Dobrota**

*Purpose: Release from quarantine is a specific activity of the blood establishments that prepare and distribute/deliver; export blood components. It involves verifying the conformity of each prepared product and establishing, based on documented objective elements, the destination of the verified products: transfer to the distribution/delivery stock, discard, quarantine maintenance, etc. The complex activity of release from quarantine is under the responsibility of a designated person. The principles of release from quarantine also apply to other specific activities of the blood establishments and hospital blood banks, with the aim of verifying the conformity of all critical items used to carry out various activities: pre-donation testing, whole blood collection, donors' biological control, pretransfusion testing protocol, etc. The paper presents the principles underlying the organization, implementation and monitoring of the release from quarantine, with examples of implementation solutions.*

*Material and method: The paper exemplifies the described activity with the organizational model in the Constanta Regional Blood Transfusion Center, for the release of blood components and critical items from quarantine. The complexity of the activity requires the identification of risks and their management. Incidents produced and unidentified/undeclared during activities completed prior to the release from quarantine can be detected; incidents can occur during the activity, with the risk, in case of non-detection, of directly or indirectly affecting the donor or the patient.*

*Results: The experience shared by the Constanta Regional Blood Transfusion supports the criticality of this activity in ensuring the quality and safety of blood components supplied to hospitals.*

*Conclusion: The release of blood components, respectively critical items, from quarantine is a specific, distinct activity, under the responsibility of the designated person; in order to ensure the conditions for organizing and carrying out this activity with the achievement of the objective – donors' safety and the safety of the patient transfused with the released blood components - it is necessary for the management to take appropriate measures: the designation of the responsible person, who will develop the appropriate documentation, will ensure the training and authorization of the designated medical personnel to perform the activity itself, the establishment of monitoring indicators and their periodic analysis, in collaboration with the quality assurance responsible.*

Regional Blood Transfusion Center Constanta

# The Impact of the Information Provided on the Interpretation of Immunohematology Tests and the Results Released. Case Presentation

**Alina Mirella Dobrota<sup>1</sup>, Anamia Panait<sup>1</sup>, Florina Mădălina Oniceanu<sup>2</sup>**

*Purpose: Adequate communication to the laboratory responsible for performing immunohematology tests of relevant information regarding a patient's history in relation with an indication for transfusion or a pregnant woman with maternal-fetal incompatibility under monitoring is essential for applying the personalized testing algorithm, obtaining consistent results and ensuring their correct interpretation. The result issued by the blood establishment immunohematology laboratory engages institutional responsibility. The attending physician establishes the monitoring and/or therapeutic plan taking these results into account.*

*Material and method: The paper presents the case of a pregnant woman alloimmunized during previous pregnancies, whose fetus required 4 intrauterine transfusions; the communication of incomplete information from the department to the immunohematology laboratory contributed to the release of a result that is not in accordance with reality, although correct (strictly related to the test result). Postpartum, the newborn was diagnosed with HDNN he received 3 transfusions of red blood cell concentrate in another medical unit. The attending physician requested advice from Constanta blood establishment regarding the immunohematological approach to the newborn and recommendations regarding the selection of blood components.*

*Results: The mother's medical history and the tests performed in the Regional Blood Transfusion Centre of Constanta, corroborated with the information and medical documents presented, allowed the clarification of the immuno-hematological characteristics of the newborn and the mother and the monitoring of the newborn's evolution. The analysis of the accumulated evidence led to the identification of apparently deficient communication among the pregnant woman/mother-attendant physicians- laboratories, despite the existence of the necessary information, since pregnancy.*

*Conclusion: Establishing clear contractual requirements regarding the accuracy of data provided with the blood samples sent for testing in the immunohematology laboratory of a blood establishment and the rigorous verification of their compliance at the laboratory level, upon receipt, as well as the interpretation of the test results taking into account the patient's history, contributes to reducing avoidable risks that may affect patient safety. Request of additional information or verification of the information provided should always be taken into consideration to avoid the risk to release incomplete or unreal results.*

<sup>1</sup>Regional Blood Transfusion Centre of Constanta, Romania

<sup>2</sup>County Clinical Emergency Hospital Constanta, Romania

# Use of the Enzyme Test in the Immunohematological Control of Donated Blood: Efficiency, Effectiveness and Impact

Alina Mirella Dobrota, Anamia Panait

*Purpose:* The paper brings to the attention of participants the need for a national evaluation of the results of the detection of anti-erythrocyte antibodies in donated blood; the current algorithm require the performance of both indirect Coombs and enzyme tests. The algorithm was implemented in January 2013, therefore, in the context of the evolution of scientific information, the accumulation of experience and evidence of testing in the system, the periodic update of the CoE/EDQM Guide for the preparation, use and quality assurance of blood components, it would be appropriate to carry out the aforementioned evaluation, followed by an update. The enzyme test has been removed from the donor testing algorithm in most blood transfusion centers in other countries, and it is no longer included in the recommendations in the EDQM Guide.

*Material and method:* The results obtained in the detection of anti-erythrocyte antibodies in donated blood in the immunohematology laboratory of the Constanta Regional Blood Transfusion Center were analyzed, over a period of 9 months (quarter IV 2024, quarter I, II 2025). The positive results in the detection and, respectively, the identification of antierythrocyte antibodies are presented, classified according to the test in which the antibodies were detected/identified: in both tests, only in the indirect Coombs test or only in the enzyme test. The identified specificities and the number of cases where, with the existing resources, the specificity could not be established, are presented. The statistical data are analyzed from the point of view of the efficacy and efficiency of performing the enzymatic test. The results of detecting irregular antibodies by both methods have a direct impact on both the availability of blood components and the management of the blood donor. Results: During the analyzed period, 7596 irregular antibody tests were performed, according to the national donor/donor testing algorithm and local testing policy. The total number of tests also includes repeated tests of regular donors. Of the total 7596, 293 (3.85%) were positive; 26 (8.8%) only in the indirect Coombs test, 243 (83%) only in the enzyme test (ficin/papain), and 25 (8.5%) in both tests. Of the 243 samples with a positive result only in the enzyme test, the specificity of the antibodies could be established for only 44 (18%), the remaining 199 (81.9%) receiving the temporary interpretation "antibodies of undetermined specificity", after resorting to all available testing resources.

*Conclusions:* The results confirm the data from the literature regarding the enzyme test, useful for the immunohematological research of samples with suspicion of a mixture of antierythrocyte alloantibodies, in donors or, especially, in patients with a history of transfusion and/or women with previous pregnancies, but with frequent uninterpretable results which, for elucidation, require financial, human, and time resources and may have a negative impact on the blood supply, respectively the suspension/exclusion of some blood donors. The extensive evaluation of the results of testing by the enzyme test in blood donors, in all blood establishments in Romania, would provide a documented database for evaluating the maintenance or elimination of the obligation to perform the enzyme test in the routine detection of irregular antibodies in blood donors.

Regional Blood Transfusion Centre of Constanta, Romania

# **The Role of the National Transfusion Network in the Management of Hematopoietic Stem Cell Donors - Achievements and Perspectives**

**Monica Dutescu<sup>1,2</sup>, Ruxandra Caisan<sup>1,2</sup>, Lorena Ulea<sup>1,2</sup>, Ana Moise<sup>1,2</sup>, Ioana Gingu<sup>1</sup>,  
Laurian Arghisan<sup>2</sup>**

*Introduction: The National Registry of Voluntary Hematopoietic Stem Cell Donors (NRVHSCD) is a public institution subordinated to the Ministry of Health, established by Government Decision no. 760/2009, which has the mission to identify and provide, at international standards, voluntary, unrelated hematopoietic stem cells (HSC) donors for patients who need bone marrow transplantation and for whom there is no compatible donor in the family. The network of units, namely Blood Transfusion Establishments where Donor Centres (DC) have been organised, testing laboratories (TL), as well as Transplantation Centres (TC) are interconnected with the registry. The accreditation of the RNDVCSH by the World Marrow Donors Association (WMDA) reflects the high level of quality standards and security data of registered donors.*

*Purpose: highlighting the role of the national transfusion network in the specific activities of recruitment, promoting, medical counselling, sample collection and testing of HSC donors, both upon registration in the registry and, subsequently, depending on request, when an extended typing (ET) or verification testing (VT) are necessary.*

*Results: In the first 10 years of activity, NRVHSCD, in collaboration with the national transfusion network, reached the target of 100,000 registered CSH donors, 90% of whom being blood donors and 10% being donors registered online, with the use of the oral mucosa collection kit.*

*Discussion: The challenges we expect are related, first of all, to the rapid and continuous technical and scientific progress in the field, which needs constant adaptability of work processes and protocols for all specific activities. In addition, to the digitalization project, Funded by the National Recovery and Resilience Program and supported by the European Union and the Romanian Government, is currently underway, aimed to transform the process of identifying compatible donors and to bring major benefits, such as reduced waiting time and improved accessibility. The collaboration between the National Transfusion Network and NRVHSCD means dedication, huge responsibility and teamwork to recognize the importance of volunteer donors who choose to save lives.*

<sup>1</sup>National HLA Laboratory, National Institute of Blood Transfusion "Prof. Dr. C.T. Nicolau", Bucharest, Romania

<sup>2</sup>National Registry of Volunteer Unrelated Hematopoietic Stem Cells Donors, Romania

# The Role of the Medical Assistant within the Bucharest Transfusion Center

E.C. Golgot, Nicoleta Cobirlie, Ingrid-Cristina Nedelcu

*Blood donation means hope, life and solidarity.*

*The blood and blood products crisis are real and continues to seriously affect the ability of hospitals to treat critically ill patients.*

*Blood is a liquid tissue that cannot be synthesized in a laboratory and can only be obtained through donation.*

*In Romania, the largest blood transfusion center is located in Bucharest, where blood donation is done in three ways: at the center's headquarters, at mobile blood donation centers (institutions, student campaigns, etc.) or at the mobile collection center - bus.*

*To organize a blood donation session, medical teams will be formed consisting of: DOCTOR - this is also the team coordinator; medical registrar; medical assistants, driver; all collaborating with other professionals in the center.*

*The entire medical team has a well-established circuit, and the key to success is constant communication with the doctor; colleagues and the blood donor; establishing a relationship of trust and mutual respect to achieve the same common goal - the successful completion of the blood donation, ensuring the quality and safety of both the blood and the donor.*

*In the donation room, the connection between the nurse and the donor must be made through empathetic and open, clear and efficient communication, helping to create an environment of trust and comfort, reducing anxiety but at the same time facilitating an exchange of precise information (the language being simple).*

*The entire medical team is made up of qualified and dedicated personnel.*

Blood Collection Laboratory - Bucharest Blood Transfusion Center, Romania

# Blood-Borne Infectious Agents

## Chikungunya Virus

**Georgeta Hanganu, Beatrice Dragomir, Mihaela Catana, Daniela Gheorghe, Anca Sbarcea**

*The increasing prevalence of blood-borne pathogens continues to threaten the safety of transfusion treatment. Currently, only a small number of pathogens are routinely tested: HBV, HCV, HIV 1+2, HTLV 1+2, Treponema Pallidum.*

*There are many others that can affect transfusion safety. Some pathogens appear seasonally and in restricted geographical areas. Currently, there are cases of chikungunya in the Caribbean, Latin America and the northern part of South America. In August 2024, the Agence régionale de santé in La Réunion, France, reported 3 cases of locally transmitted Chikungunya. In total, from the beginning of the outbreak in August 2024 to 4 May 2025, over 47,500 confirmed cases of Chikungunya have been reported on the island. The increase in the number of cases has been observed since early 2025, with the weekly number of cases increasing from 30 in late 2024 to 4,000 in the week of 10–16 March 2025, indicating an increase of over 100-fold. Chikungunya virus (CHIKV) is transmitted to humans through the bites of infected female mosquitoes, most commonly Aedes aegypti and Aedes albopictus. Although most patients recover completely from infection, occasional cases of ocular, cardiac, and neurological complications have been reported with CHIKV infections. Patients at the extremes of the age spectrum are at higher risk of severe disease, including newborns infected during birth to infected mothers or bitten by infected mosquitoes in the weeks following birth, and older adults with underlying medical conditions.*

*Conclusion: The risk of emerging pathogens is increasing, cost pressures are increasing on the transfusion system, but the desire to keep patients safe, ...implies optimal solutions...one of which is the implementation of pathogen reduction technologies.*

Prahova Blood Transfusion Center, Romania

# Quality Control of Erythrocyte Components - Hemolysis

**Georgeta Hanganu<sup>1</sup>, Monica Chiran<sup>2</sup>, Adriana Crăciun<sup>3</sup>, Beatrice Dragomir<sup>1</sup>, Mihaela Catană<sup>1</sup>, Daniela Gheorghe<sup>1</sup>, Anca Sbarcea<sup>1</sup>**

*The degree of hemolysis is an essential indicator of the quality and integrity of blood components. In the laboratory, hemolysis is an important preanalytical factor that affects the accuracy and clinical utility of many test results. Therefore, it is very important to know the hemolysis in erythrocyte concentrates or hemolysis in blood samples subjected to tests whose results are influenced or interfered with the degree of hemolysis of the sample.*

*A quality indicator for erythrocyte units is the degree of hemolysis. Hemolysis increases progressively with the storage period in erythrocyte units. However, on day 42 of storage, the free hemoglobin level should be below 0.8%. Hemolysis of red blood cell concentrates occurs during component preparation, storage, and transportation and may affect transfusion safety. Hemolysis in red blood cell concentrates is manifested by the presence of free hemoglobin in the red blood cell suspension mass, visible macroscopically in the supernatant, in plasma or additive solutions. The degree of hemolysis can be estimated by various techniques, the most common being the macroscopic/visual evaluation. Others include the spectrophotometric method, the photometric method, etc.*

*The evaluation for plasma hemoglobin is done on a low-hemoglobin plasma analyzer on the 42nd day after sampling. The percentage of hemolysis is calculated by measuring the total Hb content, hematocrit, Hb and hemoglobin content in the supernatant of red blood cell concentrates. CTS Argeş, CTS Buzău, CTS Prahova The evaluation of the degree of hemolysis in red blood cell concentrates was made as part of the quality control of blood components. The results were in accordance with the requirements.*

<sup>1</sup>Prahova Blood Transfusion Center, Romania

<sup>2</sup>Argeş Blood Transfusion Center, Romania

<sup>3</sup>Buzău Blood Transfusion Center, Romania

# The Importance of the Concept - Materiovigilance in Transfusion Centers

**Georgeta Hanganu, Beatrice Dragomir, Mihaela Catana, Daniela Gheorghe, Anca Sbarcea**

*Materiovigilance is the system for monitoring and managing adverse events related to medical devices. It involves the identification, collection, reporting and analysis of any unwanted events associated with the use of medical devices. The aim is to protect and improve patient safety by preventing or reducing the likelihood of future incidents.*

*Manufacturers are required to report to the Competent Authority serious incidents involving medical devices made available on the EU market. In Romania, the Competent Authority in the field of medical devices is ANMDMR.*

*Importers must immediately report to the manufacturer and the manufacturer's authorized representative, confirmed/suspected serious incidents involving the manufacturer's devices. Distributors must immediately report to the manufacturer, the manufacturer's authorized representative and the importer any confirmed/suspected serious incidents involving the manufacturer's devices. Healthcare professionals, patients and users must report to ANMDMR any suspected serious incident related to the medical devices they handle. Patients can inform the doctor, the economic operator from whom they purchased the device and ANMDMR when they suspect the occurrence of any serious incident, as a result of the use of the device.*

*As the use of medical devices is increasing and concerns about their safety are increasing. In order to increase patient safety, professionals in transfusion centers are also obliged to implement a material vigilance system and to report undesirable aspects related to medical devices used in the transfusion center (equipment, sanitary materials and reagents). In this context, the establishment of standard procedures for the implementation of material vigilance in transfusion centers is mandatory.*

Prahova Blood Transfusion Center, Romania

# Optimal Blood Component Stock in Uts - Desire Versus Reality

Georgeta Hanganu<sup>1</sup>, Beatrice Dragomir<sup>1</sup>, Mihaela Catană<sup>1</sup>, Daniela Gheorghe<sup>1</sup>, Anca Sbarcea<sup>1</sup>,  
Adriana Craciun<sup>2</sup>

*Ideal/optimal stock levels for blood components need to be defined to maximize blood component stock management. Ideally, a balanced approach to stock management should be used to support both patient blood requirements and patient safety, while ensuring an adequate supply of blood components for all hospitals. Hospitals should avoid practices of overstocking or “overstocking”.*

*Stock levels should be sufficient to ensure that blood components are available, when needed, to maintain the expected daily patient needs, without being excessive, resulting in high rates of discards due to expiration. Blood components should be considered valuable and limited resources, obtained with great effort, and measures should be taken to avoid their unnecessary disposal.*

*Once stock levels are calculated/determined, it is important to monitor them at regular intervals (using quality indicators) and to make a thorough review at least annually to ensure that they are still adequate.*

*Any change within the hospital that may affect the demand for blood components, such as increases or decreases in activity, services or significant changes in surgical or clinical staff, warrants a review of stock levels. Quality indicators should be implemented to monitor stocks. The ideal CTS/UTS objective => CS inputs = CS outputs + reserve/emergency stock.*

*Conclusion: It must be ensured by a calculation method that the stocks of blood components are sufficient to compensate for the interval between the time of request for components and receipt of components, in order to ensure the continuity of transfusion treatment while also avoiding waste of blood components.*

<sup>1</sup>Prahova Blood Transfusion Center, Romania

<sup>2</sup>Buzău Blood Transfusion Center, Romania

# Fecal Microbiota Transplant

**Georgeta Hanganu, Beatrice Dragomir, Mihaela Catana, Daniela Gheorghe, Anca Sbarcea**

*Donating substances of human origin that can contribute to the health of patients is a continuous and future concern of medicine. If SoHO donation began with blood donation, today the diversity of donated SoHO is increasing.*

*Fecal microbiota transplantation (FMT) is the stool transplant, and consists of the process of transferring fecal bacteria and other bacteria from a healthy person to another person. FMT is an effective treatment for Clostridium difficile infection (CDI). For recurrent CDI, FMT is more effective than vancomycin administered alone and may improve the outcome after the first infection. FMT has been used experimentally to treat other gastrointestinal diseases, including colitis, constipation, irritable bowel syndrome, and neurological conditions, such as multiple sclerosis and Parkinson's disease. The importance appears to be the use of TMF in treating patients with graft-versus-host disease (GvHD) and acute myeloid leukemia. In the United States, human feces has been regulated as an investigational drug since 2013.*

*Donor selection is rigorous to ensure the safety of the procedure. Donor screening is vital to prevent the transmission of infectious diseases. All those entering the selection process will be informed about how the process works and the purpose of their contribution and responsibility. The safety of the recipient is the primary concern. Therefore, donors will be rejected if the personal interview and/or physical examination reveals a significant relevant medical history, behaviors associated with an increased risk of contracting communicable diseases, or signs suggesting active disease. The results of fecal microbiota transplantation are promising and future-proof for collection centers.*

Prahova Blood Transfusion Center

# Validation of Standard Operating Procedures – Routine or Incomparable Difficulty?

**Georgeta Hanganu, Beatrice Dragomir, Mihaela Catana, Daniela Gheorghe, Anca Sbarcea**

*In Ministry of Health Order No. 329/2018 regarding the Norms and Requirements of good practice regarding the standards and specifications for the implementation of the quality system in health units that carry out activities in the field of blood transfusion, the concept of the validated procedure is constantly mentioned, a concept for which the literature does not offer much many details and validation examples. But the procedures must be validated. Validation means that the applicability is evaluated beforehand. In other words, the validation of a described procedure consists in performing verification actions, proving that, in accordance with the principles of good practice, the procedure leads to the expected result. The evidence must provide certainty that the manner of carrying out the activity being processed, according to the standard operating procedure described, and being implemented, will consistently lead to the desired results, which meet the specifications and ensure the quality of the results.*

*Obtaining and documenting the evidence to demonstrate that the procedure will produce the desired result according to the requirements in force, is done through practical application exercises of the standard operating procedure 3-5 times before the procedure is finalized, to observe possible deficiencies, defects gaps in applicability.*

*Consequently, after the analysis of the procedural activity, after the preparation and drafting of the pre-final form of the procedure, practical operation exercises are carried out according to the procedure, to see concretely the functionality of the procedure, the results of the procedure, to make corrections or additions and to improve the procedure, before final approval.*

Prahova Blood Transfusion Center, Romania

# **Validation of Laboratory Methods - Validation of the Method for Determining the Hemoleucogram with the Nihon Kohden Celltac G (MEK-9100) ANALYZER**

**Georgeta Hanganu, Beatrice Dragomir, Mihaela Catana, Daniela Gheorghe, Anca Sbarcea**

*The purpose of validating test methods is to demonstrate that the method is suitable for the intended purpose and that the results have acceptable precision or uncertainty.*

*Validation provides information about the repeatability and reproducibility of test methods, as well as about the influence of human, environmental, equipment and reagent factors on the uncertainty of the results.*

*The validation process has the role of verifying and establishing the limits of variability between which the method will present specific, accurate and precise results.*

*Any newly developed analysis method must be validated, as well as those that have already been developed.*

*To validate a method, several parameters are studied and evaluated: Linearity, Minimum detection limit, Precision (fidelity): repeatability - reproducibility, Accuracy, Robustness*

*The Prahova Blood Transfusion Center validated the method for determining the blood leukogram using the NIHON KOHDEN Celltac G (MEK-9100) analyzer.*

*A procedure for validating the methods for determining leukocytes, hemoglobin, hematocrit and platelets was developed. The validation of these methods was carried out taking into account the need to determine these parameters in donors and the need to determine these parameters within the quality control of blood components.*

*The results obtained during the validation of the method showed that this method can be used on the population of donors who address the transfusion center and can also be used in assessing the quality of blood components.*

Prahova Blood Transfusion Center, Romania

# Transfusion Safety and Security

**Dalia Cristina Horvat, Larisa David, Cristina Bichiș, Ramona Bornemiza**

*Introduction and objectives: With the increasing demand for blood, as well as the number of transfusions, of patients, the number of polytransfused patients has also increased.*

*As a result, it is becoming increasingly difficult to select the appropriate blood component for a patient to avoid immunization and thus a future transfusion becoming almost "impossible".*

*Through common techniques: Blood group, phenotype, DAI (detection of irregular antibodies), compatibility tests and additional techniques: TCD (direct Coombs test), extended phenotype, allo and autoadsorption techniques, we have tried to solve difficult clinical cases.*

*The main goal for performing a compatibility is to ensure, as much as possible, safe blood transfusion. Compatibility procedures should ensure obtaining the safest possible blood, at the patient's disposal, in the shortest possible time.*

*Material and methods: In this paper, we describe clinical cases encountered in our work over the past year.*

*Through common techniques: DAI, Blood group, phenotype, compatibility tests and additional techniques: TCD, extended phenotype, allo and autoadsorption techniques, we have tried to solve difficult clinical cases of polytransfused patients.*

*We have presented cases of patients with AHAI (autoimmune hemolytic anemia), polytransfused, patients on Darzalex treatment that interferes with compatibility tests, we identified immune antibodies in patients who required transfusion.*

*The objectives of a compatibility test are:*

*Detection of clinically significant antibodies;*

*Increase in transfusion security;*

*Complete the procedure in a timely manner.*

*The clinical cases from our transfusion practice that we presented, we solved using common laboratory techniques and additional techniques.*

*Results, conclusions:*

*In the conditions of increasing blood demand, as well as the number of transfusions, of patients, the number of polytransfused patients has also increased.*

*As a result, it is becoming increasingly difficult to select the appropriate blood component for each patient to avoid their immunization.*

*That is why it is important for blood transfusion centers to collaborate with transfusion units to solve difficult clinical cases.*

Hunedoara Blood Transfusion Center, Romania

# Elutia – Accessible to Everyone or an Elite Technique?

**Andreea Gabriela Ionescu<sup>1</sup>, Carmen Calugaroiu<sup>1</sup>, Carasela Ardeleanu Trusca<sup>1</sup>, Diana Ene<sup>1</sup>,  
Laura Zamfir<sup>1</sup>, Doina Gheorghe<sup>1</sup>, B. Mitroaica<sup>1</sup>, Anamia Panait<sup>2</sup>**

*Purpose: In the context of the already implementation of some innovative and detailed techniques reagents in immunohematology laboratories, do classic techniques although considered special, such as elution, still find their place and meaning, to be a real support in the differential diagnosis for certain pathological mechanisms of hemolysis or to investigate complex reactions between antigens and homologous antibodies?*

*Materials and methods: Theoretical and comparative exposition of the general characteristics of the elution techniques, respectively: methods, applicability, meaning of the results, performance characteristics, limitations, good laboratory practices, necessary: endowment / time / availability of human resources / knowledge / craftsmanship, from the perspective of usefulness and the possibility of introduction for routine performance, in as many immunohematology laboratories as possible, that serve institutions with departments with complex case studies?*

*Results: Evidence of the value of the result, of differentiation in clinical diagnosis, between AHAI and AHIM, as well as in the investigation of complex reactions between antigen and antibody.*

*Conclusions: The theoretical evaluation of the opportunity as well as the reliability of the introduction of the elution technique in the routine testing of positive TCD samples.*

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<sup>2</sup>Regional Blood Bank of Constanta, Romania

# Blood Donor Selection in 2025: How Far are We from European Standards?

## Differences Between the EDQM Guideline (Chapter 2) and Romanian Legislation - Order 1193/2007

Alexandra Ionete<sup>1</sup>, Elena Lucia Grijac<sup>2</sup>

*Purpose: To bring the criteria for blood donor eligibility in our country according with European Community standards.*

*Material and method: Donor selection is an essential step in the entire process leading to the production of high-quality blood products, a process that begins with safe blood donation.*

*The differences in blood donor selection between the current European Guidelines - European Directorate for Quality of Medicine & Health Care (EDQM edition 22 - chapter 2) and the present law in Romania, Order 1193 of July 7, 2007, will be analyzed.*

*Results: Some definitive contraindications (CI) existing in the current law become temporary contraindications in the current European guideline (e.g., syphilis becomes a temporary CI for 1 year after cure; tuberculosis becomes a temporary CI for 2 years after cure, etc.), and for some temporary CI in the current law, their duration is changed (e.g., scaling or other oral hygiene procedures have a contraindication to donate blood until the next day, not a week as in the current legislation, etc.).*

*Conclusions: Amending the legislation in force to bring it into line with current European standards is one of the challenges for the coming period.*

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<sup>2</sup>Blood Collection Laboratory - Donor Evaluation Department Blood Transfusion Center of Bucharest Municipality, Bucharest, Romania

# Tracking Silent Infections: Trends in *Treponema Pallidum* Seroprevalence Among Blood Donors in Western Romania

**Rodica Lighezan<sup>1,2</sup>, Denisa Maria Petofi<sup>3</sup>, Claudia Daniela Șerban<sup>1</sup>, Zoe Cojan<sup>1,4</sup>, P. Tănase<sup>1</sup>, Elena Kosa<sup>1</sup>, Timea Elisabeta Somogyi<sup>1</sup>, Diana Luisa Lighezan<sup>5</sup>**

*Treponema pallidum*, the etiologic agent of syphilis, is an anaerobic bacteria primarily transmitted through sexual contact, but also via direct contact with infected mucous membranes or through blood transfusion.

The study analyzed the prevalence of *T. pallidum* infection among blood donors at the Regional Blood Transfusion Center in Timisoara over a five-year period (2018–2022). All donors were serologically tested for anti-*T. pallidum* IgG, IgM, and IgA antibodies (BioRad Laboratories, Inc.), using the ELISA method.

Out of 95,249 donors tested, 248 were seropositive, resulting in an overall prevalence of 0.26%. The highest prevalence was recorded in 2018 and 2019 (0.30%), followed by a gradual decrease to 0.15% in 2022. An age-related increase in seroprevalence was observed, with the highest values found in the 41–60 age group, particularly among first-time male donors.

These findings highlight that *T. pallidum* infection remains a relevant public health concern, emphasizing the need for enhanced health education, rigorous screening protocols, and careful donor selection to reduce the risk of transfusion-transmitted infections

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<sup>5</sup>Department of Internal Medicine – Clinical Hematology, "Victor Babeș" University of Medicine and Pharmacy, Timisoara, Romania

# Possible Reactions and Risks Before and After Blood Donation. Case - CTSMB Study

**Florica Meliacă, Silvia Gina Ghencea, Georgeta Badea**

*Blood donation represents a medically safe procedure, but occasionally associated with minor adverse reactions, dependent on the physiological status of the donor and on procedural conditions. In the pre-donation period, the most frequently reported manifestations are anxiety reactions, lipothymia, and vasovagal episodes, with associated symptoms (paleness, cold sweats, nausea, vertigo). Post-donation, the most frequent reactions include asthenia, transient orthostatic hypotension, mild headache, and the appearance of a hematoma at the site of venous puncture. Severe reactions, such as prolonged syncope, marked arterial hypotension, vasovagal seizures, or local infectious complications, are rare and remit, in most of cases, under minimal medical supervision. Respecting pre- and post-donation recommendations (adequate hydration, proper food intake, avoidance of intense physical effort) constitutes essential factors for reducing the incidence of adverse reactions.*

Blood Transfusion Center Bucharest/Romania, Blood and Blood Components Collection Department

# **The Blood Transfusion Unit in the Private Medical Care Sector – From Project to Implementation and Development**

**S.I. Mociu<sup>1,2</sup>, N. Ciufu<sup>1,2</sup>, A. Mociu<sup>1</sup>, M. Vlad<sup>1</sup>, Andreea Zelca<sup>1</sup>**

*H Purpose: The aim of this paper is to share our team's experience over time, from the moment the idea of building the largest private hospital in southeastern Romania emerged, to the present day. We outline the team's journey and the challenges brought by changes and technological advancements regarding the management and operation of a blood transfusion unit in the private healthcare sector:*

*Material and methods: The concept of Ovidius Clinical Hospital took shape around 2011, with construction starting in 2013. Just nine months later, in March 2014, the hospital opened its doors, embarking on an unfamiliar path at that time, as it was the first hospital in the recent history of the region to be designed and built from the ground up.*

*Results: Today, 11 years later, Ovidius Clinical Hospital has expanded to 12,000 square meters of medical facilities, with 154 beds, following a €38 million investment. It has undoubtedly become one of the most significant players in the private medical sector in the region. The stability of the team and the strong collaboration with the Regional Blood Transfusion Center have brought substantial improvements in the quality of medical services provided to our patients.*

*Conclusions: The trajectory outlined above has matured and consolidated the team, which, having remained largely the same over the years, now possesses the experience needed to share this remarkable journey with fellow professionals.*

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# Challenges in Laboratory Diagnosis of Alloimmunization in Pregnancy

**Laura Eugenia Păcurariu<sup>1</sup>, Lavinia Anca Horvath<sup>1</sup>, Andreea Gabriela Ionescu<sup>2</sup>,  
Carmen Călugăroiu<sup>2</sup>**

*Purpose: Alloimmunization in pregnancy is an immunological process with major implications for fetal prognosis, due to the risk of developing hemolytic disease in the fetus and newborn. The purpose of this article is to highlight the importance of laboratory diagnosis in the early detection and identification of anti-erythrocytic antibodies in the monitoring of alloimmunized pregnant women.*

*Materials and methods: Clinical cases were analyzed between January and August 2025 at the Immunohematology Laboratory.*

*Initially, all pregnant women were screened for anti-erythrocytic antibodies. In cases with positive test results, specific antibody identification was performed using standardized erythrocyte panels, and clinically relevant antibodies were titrated.*

*Additionally, tests were performed to detect anti-erythrocytic antibodies in breast milk, as well as extensive phenotyping of the father.*

*Results: Analysis of the laboratory diagnosis of alloimmunization in pregnancy revealed multiple challenges. Antibody titration does not always correlate with the severity of fetal disease, especially in the case of non-D antibodies, making it difficult to estimate risk based on serological titer.*

*Conclusion: Even though anti-D antibodies were once the main cause of hemolytic disease of the newborn, the widespread administration of anti-D immunoglobulin prenatally and postpartum has led to a significant decrease in the prevalence of alloimmunization to the D antigen during pregnancy.*

*Maternal alloimmunization to other anti-erythrocytic antigens continues to play an important role in hemolytic disease of the newborn, as there are no prophylactic immunoglobulins available to prevent the formation of these antibodies.*

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<sup>2</sup>Fundeni Clinical Institute, Bucharest, Romania

# Optimizing the Detection of Blood-Borne Infections in Blood Donors: ELISA VS. Chemiluminescence

**Irina Gabriela Răchită<sup>1</sup>, LCR – MTS<sup>2</sup>**

*Aim: Transfusion safety relies not only on compliance with analytical standards but also on the use of technologies adapted to the real needs of the laboratory. This study aimed to compare the performance of two automated chemiluminescence-based serological platforms, Elecsys (Roche) and Alinity s (Abbott), with Evolis (Bio-Rad), the system currently used in the laboratory.*

*Material and method: The three instruments operate based on different principles: Evolis uses the ELISA method with colorimetric detection, Elecsys is based on ECLIA technology, and Alinity s uses CMIA. The evaluation of Elecsys was carried out by testing 2317 samples from first-time donors in parallel with Evolis for HBsAg, HCV Ag/Ab, HIV Ag/Ab, HTLV I/II Ab and Treponema pallidum Ab. For Alinity s, 1006 samples from first-time donors were analyzed, also in parallel with Evolis, for HBsAg, HIV Ag/Ab, HTLV I/II Ab and Treponema pallidum Ab.*

*Results: The concordance between chemiluminescence and ELISA was very good, and reactive samples were further investigated according to national confirmation procedures, which validated the reliability of the findings.*

*Conclusions: All three platforms proved effective in screening transfusion-transmissible infections, with no major differences in terms of sensitivity and specificity. The overall level of safety and reliability was comparable, and the choice of the appropriate system depends on the context of each laboratory: ELISA remains a solid and validated option, while chemiluminescence-based platforms may provide additional benefits in settings with high donor volumes and increased operational demands that justify a higher degree of automation.*

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# Legislative Updates and Strategic Perspectives in Civil-Military Cooperation, in the Blood Transfusion Field

**Maria-Cristina Ranetti, Roxana-Gabriela Pricop, M.E. Ion, Beatrice-Cristina Ivan,  
Adela-Elena Zamfirescu**

*The legislation governing the medical field of blood transfusion in Romania is in the process of being updated and is part of the reorganisation of the national blood transfusion system. The updating of the legislation reflects on the one hand, the European requirements regarding the quality of human blood and blood components, which are reflected in guidelines and regulations adopted at EU level, and, on the other hand, the permanent evolution of this medical field of strategic importance. The paper aims to highlight the legal regulations for the period 2024-2025 and to sensitise decision makers to the importance of this niche medical field in the light of these regulations and the current geo-political context.*

"Col. Prof. Dr. Nicolae Nestorescu" Blood Transfusion Center, Bucharest, Romania

# Sensitivity of Coagulation Factors V and VIII in Plasma Components

**Luminita Rusen, Paula Badea**

*Introduction: Coagulation factor V is a plasma and platelet glycoprotein with a central role in the coagulation process. It is almost completely consumed in both coagulation pathways. Most coagulation factors are stable at refrigeration temperatures except for factors VIII and V. Important steps in their preservation are the freezing and thawing of plasma. According to some authors, FV value also seems to be sensitive to storage conditions. If fresh frozen plasma (FFP) is not stored at a temperature lower than -25°C, FVIII levels decrease rapidly in the first 24 hours, while FV decreases more slowly.*

*The purpose of the paper is the evaluation of FV and FVIII levels in FFP and leukocyte-depleted FFP (LD FFP) units.*

*Material and method: 275 plasma units were randomly selected, of which 201 FFP and 74 LD-FFP, from those sent by the Transfusion Centers for hemostasis quality control. All selected samples were tested to determine FV and FVIII levels, using the one stage method on a Sysmex CS 2500 automatic coagulometer during the period April 2024 - March 2025.*

*Results and discussion: FVIII and FV dosing was performed on 195 units of FFP and 74 units of LD-FFP. All plasma units were stored for a maximum of one month after blood processing. The values of the 2 coagulation factors tested were variable. Thus, for FFP the level of FVIII was between 25-155% and for FV it varied between 55.3% and 144.8%. For LD-FFP the level of FVIII was between 38.8-151.8% and for FV it varied between 61.2% and 165.5%.*

*It is apparent that regardless of the type of simple or leukocyte-depleted plasma product, the minimum level of FVIII is always lower compared to FV. In addition, the units that have a non-compliant level are fewer (4.46%) for FV compared to 22.2% for those with FVIII<70% (non-compliant).*

*Conclusions:*

- *The level of FVIII decreases faster than FV which decreases more slowly.*
- *In case of low FVIII levels, FV can also be tested.*
- *Changes in coagulation parameters also require analysis by the technical processing team because they can be influenced either by the donor's coagulation profile or by the freezing or cold chain conditions regarding the storage or transport of plasma units.*

National Institute of Blood Transfusion "Prof. dr. C.T. Nicolau" Bucharest, Romania

# Approach and Management of Blood Transfusion Challenges – Immunohematology Cases Presentation

R. Suciu, A. Stancu, I. Cojocaru, M. Cosma, M. Ailenei, A.I. Zagrean, L.E. Grijac

*Background:* Determining the true cause of immunization is sometimes challenging and requires a complex approach through performance of additional testing and the most accurate interpretation of results, in order to identify the presence of potential alloantibodies, those most frequently involved in the development of HDFN (hemolytic disease of the fetus and newborn) and in posttransfusion adverse reactions.

*Methods:* We retrospectively evaluated 1035 cases received at the Bucharest Blood Transfusion Center between January 2025 and August 2025. Among the tests used, DAI (detection of irregular antibodies) was performed, and, subsequently, if these were present, IAI (identification of irregular antibodies) was carried out. In cases where the specificity of an antibody could be identified, extended antigen phenotyping was required. The DAT (direct antibody test) supports the etiological investigation of hemolytic anemia, posttransfusion reactions, or an autoimmune disease.

*Results:* This study revealed that 32.46% of patients were found to be immunized, as follows: 10,80% had alloantibodies with specificity, 2,03% had with specificity autoantibodies, 4,87% had autoantibodies and nonspecific antibodies and 14,76% had nonspecific antibodies. The particularities of the selected cases have required the implementation of a complex testing protocol aimed at reducing the incidence of possible posttransfusion hemolytic reactions.

*Conclusions:* To sum up, the use of the autocontrol test is important, as it can, in correlation with the DAT result, indicate the possible presence of autoantibodies or alloantibodies. However, to confirm their presence, additional tests are necessary, depending not only on the transfusion history, but also on the clinical and paraclinical data of the patient.

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# Transfusion Therapy in Hematologic Diseases: Thresholds, Chemotherapy, and Associated Toxicities

Cezara Tudor<sup>1</sup>, Alina Mirella Dobrota<sup>2</sup>

*Objective: Transfusional therapy remains a cornerstone in managing patients with hematological malignancies, yet current transfusion thresholds are not fully tailored to chemotherapy intensity or associated toxicities. This study aims to assess the correlation between chemotherapy regimens and transfusion needs, focusing on optimizing blood component selection and minimizing adverse effects.*

*Material and method: We analyzed various chemotherapy regimens used in patients with hematological malignancies, assessing transfusion thresholds, frequency of severe cytopenias, and types of blood components used (standard vs. leukoreduced/irradiated red cell concentrates). Transfusion-related toxicities and iron overload were also evaluated.*

*Results: Intensive myelosuppressive regimens (e.g., BEACOPP, Hyper-CVAD) required significantly more transfusions compared to moderate regimens (e.g., R-CHOP, Bendamustine). The use of leukoreduced and irradiated blood components reduced the incidence of acute transfusion reactions and metabolic complications. Correlating transfusion thresholds with chemotherapy intensity may improve both treatment efficacy and patient quality of life.*

*Conclusions: Establishing transfusion guidelines adapted to chemotherapy intensity is essential to reduce transfusion-related toxicities and long-term risks such as iron overload. Personalized transfusion thresholds and optimized blood component selection may decrease transfusion dependency and improve therapeutic outcomes.*

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<sup>2</sup>Regional Blood Transfusion Center Constanța, Romania

# Renal Involvement in Thalassemia: Mechanisms, Clinical Features and Management Strategies

**Maria Daniela Voicu, Cristina Ioana Mitru, Larisa Diana Nitu, Iulia Constantinescu**

*Renal dysfunction is an increasingly recognized complication in patients with thalassemia, particularly as life expectancy improves due to advances in transfusion and chelation therapy. The underlying mechanisms are multifactorial, including chronic anemia, iron overload, oxidative stress, hypoxia, and nephrotoxicity of iron chelators. Early renal involvement may manifest as glomerular hyperfiltration, proteinuria, and proximal tubular dysfunction, and may progress to chronic kidney disease (CKD) if left undetected.*

*This presentation will explore the pathophysiology of renal impairment in thalassemia, highlight clinical manifestations and diagnostic tools (including emerging biomarkers), and outline current approaches to monitoring and management. Special attention will be given to differences between thalassemia major and intermedia, and the implications of iron chelation protocols. A multidisciplinary strategy involving both hematologists and nephrologists is crucial to prevent long-term renal complications in this vulnerable population.*

*Keywords: thalassemia, renal dysfunction, iron overload, chelation therapy, chronic kidney disease, biomarkers*

National Institute of Blood Transfusion "Prof. dr. C.T. Nicolau" Bucharest, Romania

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# Patient Blood Management (PBM)

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**Maria Daniela Voicu, Larisa Diana Nitu, Cristina Ioana Mitru, Iulia Constantinescu**

*Patient Blood Management (PBM) is an evidence-based, multidisciplinary approach aimed at improving patient outcomes by optimizing the use of autologous blood and minimizing reliance on allogeneic transfusions. PBM is structured around three key pillars: optimization of erythropoiesis, minimization of blood loss, and improvement of the patient's tolerance to anemia.*

*Effective implementation of PBM has been associated with reductions in transfusion-related complications, shorter hospital stays, and lower healthcare costs, while enhancing patient-centered care. Given the global challenges related to blood supply and transfusion safety, PBM is increasingly recognized as a cornerstone of modern clinical practice.*

*This presentation will highlight the core principles of PBM, review clinical evidence supporting its effectiveness, explore implementation challenges, and discuss its applicability and integration into clinical practice in Romania and beyond.*

*Keywords Patient Blood Management, transfusion, anemia, erythropoiesis, surgery, blood conservation, patient safety*

National Institute of Blood Transfusion "Prof. dr. C.T. Nicolau" Bucharest, Romania
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# The Role of Multidisciplinary Teams in the Management of Transfusion-Dependent Patients: an Integrated Approach to Transfusion Safety

**Maria Daniela Voicu, Larisa Diana Nitu, Cristina Ioana Mitru, Iulia Constantinescu**

*Introduction: Blood transfusion is a common medical procedure, yet it carries significant risks when not properly indicated or monitored. In this context, the involvement of multidisciplinary teams has become essential in ensuring safe and effective transfusion practices.*

*Objective: To assess the role of multidisciplinary teams in optimizing the transfusion process and reducing associated risks in transfusion-dependent patients.*

*Method: Narrative review of the current literature, supported by clinical examples and aligned with international guidelines on transfusion medicine and patient blood management (PBM).*

*Results: Multidisciplinary teams—including clinical physicians, transfusion medicine specialists, nurses, pharmacists, and quality/risk management personnel—contribute to: accurate evaluation of transfusion indications, strict adherence to compatibility protocols, early detection and management of adverse reactions, implementation of PBM principles tailored to each patient.*

*Conclusion: The integration of multidisciplinary teams in the management of transfusion-dependent patients is a key component of modern, patient-centered care. Their collaboration enhances transfusion safety, promotes judicious use of blood products, and should be regarded as a standard practice in healthcare institutions.*

National Institute of Blood Transfusion “Prof. dr. C.T. Nicolau” Bucharest, Romania

# The Friendly Robots Around Us (Comparative Study)

**Alexandra Zăgrean**

*Objective: The aim of this study was to monitor and to compare various automatic in the CTSMB for a period of 10 months. These “robots” execute a great variety of test procedures on highest level of security and flexibility.*

*Material/method: Equipments: the Ortho Vision fully automated analyzer (Ortho), fully automated system Qwalys (Diagast), fully automated IH 1000 (Biorad).*

*A number of 10640 samples were taken and processed for ABO/Rh/phenotype/DAI tested routinely with micro plates and cassettes. Ortho Vision use the Ortho BioVue column agglutination of glass beads contained in a cassette, IH 1000 use the DiaMed column agglutination in gel end Qwalys 3 use EM technology. All automatic systems deliver results at a high resolution. Samples were monitored by using data processing system and data archives studies.*

*Results:*

- 128 samples ( 2,27 % ) DAI positive;
- 165 samples (1,55 %) were D weak and D partial from different category, tested by Coombs;
- 10640 samples processed from ABO with 100% accuracy.

*Conclusion: The robotically systems are especially good for CTS with a high number of donors. The benefits are precision and accuracy giving the ability to monitor every step in the process and created a real time interaction to review resultants. Reduces manual interaction and minimizes the potential for error eliminating the subjectivity of the human factor!!! The fact that they can be connected to the computer system CTS Manager it simplifies and ensures safe data transmission.*

Lab. Imunohematologie Bucharest, Blood Transfusion Center Bucharest, Romania

# Occult Hepatitis B Among Donors - 4 Years of Experience in Blood Testing By the NAT Method, in the C.T.S. of the M.Ap.N.

Adela-Elena Zamfirescu, Irina Butte

*Aim: Occult hepatitis B infection (OBI) represents a challenge for transfusion safety, since donors are HBsAg negative but may still have detectable viral DNA, with a potential risk of transmission. The aim of this study was to evaluate the prevalence of OBI among blood donors tested by nucleic acid testing (NAT) and to identify associated serological characteristics.*

*Material and method: Since 2021, all blood donors have been tested by nucleic acid amplification techniques (NAT) for HBV, HCV and HIV, in parallel with standard serological screening. We analyzed the results over a 4-year period, focusing on regular donors. Data on HBsAg, anti-HBc antibodies and the evolution of NAT results over time were included.*

*Results: During the study period, a small number of donors who were initially NAT negative later became NAT positive for HBV. All these donors were HBsAg negative but anti-HBc Ab positive, confirming previous exposure to the virus. The cases identified suggest the existence of occult hepatitis B with intermittent viral replication. The introduction of NAT enabled the detection of these cases, thereby improving blood safety.*

*Conclusions: OBI is also present among blood donors, although with low prevalence. Its consistent association with anti-HBc antibodies underlines the role of this marker as an indicator of past exposure. NAT testing is essential to identify donors with detectable HBV DNA despite negative HBsAg, and represents an important step in strengthening transfusion safety.*

Blood Transfusion Center of the Ministry of National Defense "Col. Prof. Dr. Nicolae Nestorescu", Bucharest, Romania

# Between Cardiotoxicity and Disease Progression: Challenges in the Management of Relapsed FLT3-ITD AML

**Maria Bacanu<sup>1</sup>, Meilin Omer<sup>1</sup>, Mihaela Andreescu<sup>1, 2</sup>**

*Objective: To describe a case of relapsed FLT3-ITD acute myelomonocytic leukemia (AML M4) complicated by severe cardiovascular and infectious comorbidities, which limited therapeutic choices and required an individualized approach.*

*Methods: A 61-year-old woman with hypertension presented with headache, dizziness, chest pain, and persistent diarrhea. Laboratory tests showed mild anemia, marked leukocytosis with >80% blasts, and thrombocytopenia. Immunophenotyping, molecular, and cytogenetic studies confirmed AML M4 FLT3-ITD.*

*Results: Induction therapy with cytarabine and anthracycline ("5+2") was initiated but complicated by gastrointestinal sepsis and severe cardiotoxicity (EF 32%), precluding FLT3-targeted therapy. The disease relapsed, and although standard protocols indicated intensive reinduction, treatment with a hypomethylating agent plus venetoclax was chosen due to worsening cardiac function and high toxicity risk. The patient's course was unfavorable, with EF decline to 16% and recurrent syncopal episodes. Cardiology recommended discontinuation of antileukemic therapy, as risks outweighed potential benefits, restricting management to supportive care.*

*Conclusions: This case underscores the challenges of managing relapsed AML in multimorbid patients. Cardiotoxicity and infection-related complications critically limited therapeutic options. Despite interdisciplinary collaboration, the outcome reflected the constraints of treating an aggressive hematologic malignancy in a fragile clinical context.*

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# Single-Center Experience with Asciminib in Previously Treated Chronic Myeloid Leukemia Patients in Routine Clinical Practice

Mara-Caterina Bălan<sup>1</sup>, Alexandra Damaschin-Țoiu<sup>1</sup>, M.E. Lăpădat<sup>1,2</sup>, Irina Nicoleta Triantafyllidis<sup>1,2</sup>, Anca Mariana Ciobanu<sup>1</sup>, Marina Dănilă<sup>1,2</sup>, Carmen Șaguna<sup>1,2</sup>, A. Turbatu<sup>1,2</sup>, A. Coliță<sup>1,2</sup>, Oana Stanca<sup>1,2</sup>

*Objective:* Asciminib is the first inhibitor with a unique STAMP mechanism (specifically targeting the ABL myristoyl pocket), distinct from previously used ATP-competitive tyrosine kinase inhibitors (TKIs) for chronic myeloid leukemia (CML). It is approved for adult patients with chronic-phase CML previously treated with at least two TKIs or harbouring the T315I mutation. Given the therapeutic needs of patients exposed to multiple prior lines and the lack of real-world data, we assessed the effectiveness and safety of Asciminib in a cohort treated at the Colțea Hematology Clinic.

*Materials and methods:* We conducted a retrospective, descriptive study including 10 patients who initiated Asciminib between October 2023 and August 2025. We collected data on demographics, prior therapy lines, reasons for switching, molecular responses at 3, 6, and 12 months, adverse events, dose reductions, and treatment interruptions.

*Results:* Sex distribution was equal. The median age at initiation was 70 years, and the median interval from diagnosis to Asciminib start was 7.5 years. Before Asciminib, 30% of patients had received 4 TKI lines and 50% had received 3 lines. The last TKI used was Nilotinib in 50% and Bosutinib in 40% of patients. At 3 months, 4 patients achieved an optimal response (BCR-ABL1 <10% IS), of whom 3 had a molecular response (BCR-ABL1 <1% IS). At 6 months, the profile was maintained: 4 patients with an optimal response, including 2 with a molecular response. One patient achieved a deep molecular response (BCR-ABL1 <0.1% IS) at 3, 6, and 12 months. One patient was a non-responder at 12 months and discontinued therapy. The main adverse events were neutropenia and thrombocytopenia; one patient had a subconjunctival hemorrhage associated with thrombocytopenia requiring dose reduction, and another had thrombocytopenia necessitating periodic treatment holds. At the most recent clinic assessment, 8 of 10 patients remained on treatment; Asciminib was discontinued in 2 patients due to disease progression or toxicity.

*Conclusions:* In routine practice, Asciminib shows an efficacy and tolerability profile comparable to pivotal clinical trials, reinforcing its role as a valuable option for patients with CML with progression after multiple TKIs. Long-term monitoring is needed to evaluate the durability of responses.

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# An Atypical Case of Richter's Transformation

**Daniela-Marina Bucur Mihăilescu<sup>1</sup>, R. Stoia<sup>1</sup>, Camelia Dobrea<sup>1,2</sup>, D. Coriu<sup>1,2</sup>**

*Introduction: Richter's transformation in chronic lymphocytic leukemia (CLL) is a rare complication with unfavorable prognosis, given its aggressive course and poor response to typical chemoimmunotherapy.*

*Methods: A 52-year-old woman diagnosed with CLL in 2022 developed diffuse large B cell lymphoma (DLBCL) as Richter transformation after 2 years of treatment with acalabrutinib and was treated in our clinic.*

*Results: The patient was diagnosed with CLL in 2022; she had unmutated IGHV status without other high-risk features. She received treatment with Acalabrutinib, with good initial response. After 2 years of treatment, she presented with generalized lymphadenopathy as well as reappearing lymphocytosis. Two different lymphocyte populations were identified: a circulating CD5, CD79b positive CLL clone and a CD5 negative PD1 positive DLBCL Richter transformation clone within a lymph node. She was treated initially with Venetoclax, with no response on the lymphadenopathies, afterwards with the Pola-R-CHP regimen, with complete response on both clones. She then proceeded to autologous stem cell transplantation (autoSCT) and is awaiting evaluation of response.*

*Conclusions: Lymphocytosis reappearing while on treatment in the context of CLL along with enlarged lymph nodes does not always indicate a single entity and a biopsy should routinely be ordered, in order to exclude an aggressive transformation. AutoSCT should be considered as a treatment option, being associated with fewer complications than allogeneic transplantation.*

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# Reclassification of TP53 Variants in Oncogenetics

**Elena Bulancea<sup>1</sup>, Ștefania Iordache<sup>1</sup>, Cerasela Jordan<sup>1,2</sup>, Onda-Tabita Calugaru<sup>1,2</sup>**

*Introduction: Variants of uncertain significance (VUS) in cancer predisposition genes such as TP53 pose a challenge for clinical interpretation. The DNA-binding domain (DBD) is critical for protein function, and mutations in this region may have major functional impact.*

*Materials and methods: We extracted approximately 100 VUS variants located in the TP53 DBD from the ClinVar database. Variants were re-evaluated according to ACMG/AMP criteria and available literature.*

*Results: More than half of the variants were reclassified as "pathogenic" or "likely pathogenic" highlighting the clinical relevance of their position in a key functional domain.*

*Conclusions: Reclassification of TP53 variants in the DBD underscores the importance of periodic VUS reassessment and integration of functional and bibliographic data for robust clinical interpretation.*

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# A Case of Chronic Myeloid Leukemia Associated with Uterine Corpus Neoplasm

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*Introduction: Chronic myeloid leukemia (CML) is the first malignant hematological disease to benefit from molecularly targeted treatment with tyrosine kinase inhibitors (TKIs), leading to a significant increase in overall survival and quality of life in patients with this disorder.*

*Case presentation: We present the case of a 64-year-old patient from a rural area with multiple cardiovascular comorbidities, grade II obesity, and type 2 diabetes mellitus, diagnosed in 2007 in the Clinic of Hematology from Craiova with chronic phase CML, Ph cr. in 90% of the examined metaphases, BCR-ABL1 transcript of 79,80% IS, Sokal score: intermediate risk. Cytoreductive treatment with hydroxyurea, uricosuric, and hydration was initiated, followed by treatment with IFN $\alpha$ -2b, 3xMIU/day s.c. Since June 2008, treatment with imatinib mesylate 400 mg/day, then 600 mg/day, was administered, however, not even a complete hematological response was reached. In 2010, she was switched to 2<sup>nd</sup> gen. TKI nilotinib 800 mg/day. After 6 months of treatment, the BCR-ABL1 transcript level decreased from 73,719% to 37,810%, and after 5 years of treatment with nilotinib, RMM was obtained. In April 2018, the patient presented with QT interval prolongation; nilotinib was interrupted, and 6 months after interruption, the BCR-ABL1 transcript level was 76,840% IS. Treatment with reduced-dose nilotinib was given, with a BCR-ABL1 transcript reduction after 3 months to 0.078% IS. In March 2021, in the midst of the COVID-19 pandemic, she was diagnosed with inoperable endometrial cancer of the uterine corpus T3N1M0 stage IIIC, for which 12 courses of chemotherapy and radiotherapy (total dose: 50.4 Gy/28 sessions) were administered; however, there was an unfavorable evolution, with the development of lung metastases, cardiorespiratory failure, and death. At the time of death, the patient was in MR4 molecular response, BCR-ABL1 transcript level of 0.0042% IS.*

*Conclusion: Targeted therapy with TKI has significantly improved overall survival and quality of life in CML patients. However, the particularities of each case, the mutational status, the presence of comorbidities, the intimate mechanisms that are established between these factors and the hematological disease, the drug interactions between TKI and the specific treatment of each comorbidity, significantly influence the time of response to treatment, the optimal dose of TKI with the best efficiency and tolerability and finally the duration of overall survival and quality of life.*

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# Subcutaneous Panniculitis-Like T-Cell Lymphoma: A Possible Cause for Complex Neurological Manifestations

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*Introduction: Subcutaneous panniculitis-like T-cell lymphoma (SPTCL) is a rare form (<1%) of non-Hodgkin lymphoma (Alsomali D.Y. et al, 2023), which is externalized through multiple subcutaneous plaques and nodules, typically on the lower and upper extremities, or trunk. Neurologic symptoms have been documented in SPTCL patients (Jing Xu et al, 2022).*

*Case presentation: A 34-year-old patient without major pathological antecedents presented to the ORL department, in 2023, with a left genian mass, complaining of paresthesia. The CT exams revealed a diffuse thickening of the soft parts at this level. The left genian tumor is excised, and following the anatomopathological examination the diagnosis of SPTCL is made. In 2024 he is diagnosed with progressive multifocal neuropathy, common peroneal nerve palsy and bilateral ulnar nerve paresis. He follows a treatment with Alasod, Pentoxifylline and Intravenous Immunoglobulins (IVIg). In 2025, indurated subcutaneous nodules appear on his trunk, head and limbs and he accuses gait disturbances. The PET CT exam revealed hepatosplenomegaly and lymph nodes (with a Deauville score of 4), with infiltrative appearance, in the adipose panicles. A 3-stage chemotherapy course is started, the nodules recede and mobility improves. The patient is prepared for an autologous STEM cell transplant.*

*Conclusion: Due to the rarity and frequent association with autoimmune diseases (as lupus erythematosus) SPTCL treatment represents a medical challenge. Although the subcutaneous plaques are painless, the local swelling and inflammation can affect the surrounding tissue, including the nerve cells, however the etiology of neurological manifestations in SPTCL patients is complex.*

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# Why Not Treat MZL with Plasmocytic Differentiation as a Myeloma?

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*Marginal zone small B-cell non-Hodgkin lymphoma with plasmacytoid differentiation is a rare indolent lymphoma subtype, typically treated with rituximab, an anti-CD20 monoclonal antibody. However, certain clinical contexts require off-label therapeutic alternatives. Plasmacytoid differentiation involves the transformation of some lymphoma cells into plasma cell-like cells, which may express specific markers (e.g., CD138) and secrete monoclonal immunoglobulins. This cellular heterogeneity may affect prognosis and therapeutic strategy. We report the case of a 46-year-old patient diagnosed in December 2017 with stage IV marginal zone small B-cell lymphoma with plasmacytoid differentiation and kappa light chain restriction. After standard R-CHOP treatment failed to achieve remission, a CyBorD regimen was initiated, followed by thalidomide, bortezomib, hematopoietic stem cell harvesting, and autologous transplantation in September 2018. The patient achieved clinical remission. This case highlights the potential use of treatment regimens adapted from multiple myeloma protocols as an alternative approach in marginal zone non-Hodgkin lymphoma with secretory features. Further studies are needed to validate this therapeutic strategy.*

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# Large B-Cell Diffuse Non-Hodgkin Lymphoma with Primary Cardiac Involvement

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*Objective:* Presentation of a case of large B-cell non-Hodgkin lymphoma with primary involvement of the heart (PCL) and a chronological overview of the clinical course and therapeutic management.

*Methods:* Retrospective clinical case of a 62-year-old female patient, diagnosed and treated in our clinic between May 2024 and June 2025.

*Results:* The 62-year-old patient presented with severe exercise intolerance and chest pain, for which she was admitted to the Cardiology Clinic. Imaging studies revealed the presence of a cardiac tumor mass. Surgical excision of the tumor from the right atrium through median sternotomy was performed at Pelican Hospital Oradea (05.2024). Histopathological examination confirmed the diagnosis of diffuse large B-cell non-Hodgkin lymphoma, NOS, non-germinal center subtype. The first cycle of R-DA-EPOCH treatment was initiated on 28.05.2024. On the third day of treatment, the patient developed paroxysmal atrial flutter, which was pharmacologically converted to sinus rhythm. Six cycles of R-DA-EPOCH were administered without achieving a favorable response. Second-line treatment with Polatuzumab-R-BENDA was initiated, with the patient undergoing six cycles completed in April 2025. PET-CT confirmed progression of the tumor process with invasion of the superior mediastinum and left lung. Specific treatment with Epcoritamab was initiated. The patient's condition progressively deteriorated, with the onset of devastating complications: severe bone marrow aplasia with profound thrombocytopenia ( $2 \times 10^3/\mu\text{L}$ ) manifested by multiple cerebral hemorrhagic suffusions, severe neutropenia ( $0.00 \times 10^3/\mu\text{L}$ ) with lung-derived sepsis evolving to septic shock, multiple organ failure, and death.

*Conclusions:* Diffuse large B-cell non-Hodgkin lymphoma with primary cardiac involvement represents a rare entity with an extremely aggressive clinical course. This case illustrates the complexity of primary cardiac lymphoma management and the major risks associated with treatment. PCL remains a significant challenge for hematologists.

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# Beyond Routine Haemostasis Tests: Diagnosing Congenital Factor XIII Deficiency

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*Congenital Factor XIII (FXIII) deficiency is an exceedingly rare bleeding disorder, with a global prevalence estimated at approximately 1 in 2 million individuals and roughly over 1,000 cases reported worldwide. Unlike most coagulation abnormalities, routine haemostasis screening tests, including prothrombin time (PT), activated partial thromboplastin time (aPTT), and fibrinogen levels, are typically normal in FXIII deficiency, complicating timely diagnosis. FXIII plays a critical role in cross-linking fibrin and stabilizing the clot; its deficiency can result in life-threatening bleeding, impaired wound healing, and recurrent pregnancy loss in women of childbearing age. In plasma, FXIII exists as a heterotetramer composed of two catalytic A subunits and two carrier B subunits (A2B2 complex), whereas the cellular form is a homodimer of two A subunits, contributing to its critical function in tissue repair. Most congenital FXIII deficiencies are caused by mutations in the F13A1 gene, inherited in an autosomal recessive pattern, leading to functional loss of FXIII activity and clinically manifesting as severe or uncontrolled bleeding despite normal routine coagulation parameters. Lifelong replacement therapy is required for management, with several treatment options available, including plasma-derived FXIII concentrates, recombinant FXIII, cryoprecipitate, and fresh frozen plasma (FFP), each with specific indications, dosing regimens, and potential adverse effects.*

*The following clinical case describes a congenital factor XIII deficiency in a young female patient, with a delayed diagnosis, a history of multiple episodes of hemoperitoneum, and one episode of TRALI following treatment with fresh frozen plasma. She is currently being monitored under recombinant factor XIII therapy.*

*Keywords: factor XIII deficiency, recombinant factor XIII therapy, congenital bleeding disorder, TRALI*

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# Mortal Challenges in Acute Leukemia – Mucormycosis. Clinical Case

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*Background: Acute myeloid leukemia (AML) is a malignant pathology characterized by the failure of differentiation and uncontrolled proliferation of immature myeloid precursors (blasts) in the bone marrow. This leads to the suppression of normal hematopoiesis, resulting in severe cytopenias: anemia, thrombocytopenia, and most critically from an infection perspective, neutropenia. Mucormycosis represents a lethal fungal threat caused by ubiquitous saprophytic fungi of the order Mucorales which have a pronounced vascular tropism, known for their capacity for angioinvasion.*

*This case report presents the complex evolution of a patient diagnosed with AML and Mucormycosis.*

*Clinical Case: A 49-year-old patient, with no risk factors and a favorable ECOG index, was diagnosed with AML in the Hematology Clinic of Municipal Hospital from Timisoara. She underwent multiple lines of treatment with no therapeutic response, due to infectious complications. Erythema is observed in the region of the nasal pyramid and black discharge at the level of the middle turbinate, suggestive of necrosis. During the evolution, a crusty lesion is noted that compromises the hard palate, an ulcerative lesion at the inner corner of the right eye with periorbital edema and cellulitis that fistulizes from the ethmoid, and extensive necrotic crusts adherent to the entire lateral wall of the right nasal fossa. Daily treatment with Isavuconazol 200 mg/day was initiated, and post-mucormycosis necrosis was excised from the right nasal fossa. Intraoperative examination revealed necrosis in the oral cavity, with involvement of the nasal septum, nasal turbinates, hard palate mucosa, skin of the nasal pyramid, eyelids, and the right eyeball.*

*Conclusion: This case highlights that Mucormycosis in patients with AML is a complex clinical entity with an extremely high mortality rate. Rapid diagnosis and an aggressive therapeutic approach that combines systemic antifungal therapy with surgical debridement are the only strategies that can significantly improve survival chances in this devastating pathology.*

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# VEXAS Syndrome: The Patient's Helplessness in the Face of a Rare Disease

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*Objective: To concisely present VEXAS and VEXAS-like entities, highlighting etiology, clinical manifestations, diagnostic challenges, and therapeutic options through a synthesis of the literature and a case report. VEXAS syndrome (Vacuoles, E1 enzyme, X-linked, Autoinflammatory, Somatic) is a systemic autoinflammatory disorder caused by acquired somatic mutations in UBA1, a gene essential for the ubiquitin–proteasome pathway. It predominantly affects men and combines rheumatologic and hematologic manifestations. Due to its clinical complexity, diagnosis can be challenging and requires a multidisciplinary approach.*

*Materials and methods: Review of the specialized literature and analysis of a patient admitted to our clinic.*

*Results: A 58-year-old man presented with three days of right periorbital edema, fever, bilateral auricular chondritis, and a disseminated erythematous rash (round-to-oval, indurated lesions with a purpuric center); pancytopenia with preexisting macrocytic anemia, a marked inflammatory syndrome, and mild hepatic cytolysis. Clinical course: complete remission of symptoms under oral corticosteroid therapy, with persistent pancytopenia and recurrent flares (febrile erythema, periorbital edema, upper-limb edema, and cutaneous hyperreactivity at venipuncture sites). Investigations: bone marrow aspirate suggestive of myelodysplastic syndrome, RAEB-2; intracytoplasmic vacuoles in myeloid precursors. Genetic testing: UBA1 sequencing negative; diagnosis of VEXAS-like syndrome. Treatment: azacitidine (myeloablative) and a tapering corticosteroid regimen, with favorable evolution.*

*Discussion: The existence of VEXAS-like cases, with highly suggestive clinical features but no identifiable mutation, supports mechanistic heterogeneity and underscores the need for multidisciplinary management.*

*Conclusions: Early recognition of VEXAS/VEXAS-like is essential. Immunosuppressive therapies and myeloablative treatment—and, in selected cases, hematopoietic stem cell transplantation—may improve prognosis. Further studies are needed.*

*Keywords: VEXAS, UBA1, VEXAS-like, myelodysplasia, azacitidine, corticosteroid therapy*

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# A Case Of Hodgkin's Lymphoma Associated with Pulmonary Tuberculosis

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*Introduction: Hodgkin's Lymphoma (HL) represents a distinct lymphoproliferative disorder due to the fact that the neoplastic cells are relatively few in proportion, being surrounded by a polymorphic reactive infiltrate. The nodular sclerosis subtype, a form of classical HL, is the most common among patients with mediastinal tumor masses, sometimes raising diagnostic difficulties with pulmonary tuberculosis, which can also present with hilar and mediastinal lymphadenopathy. In such cases, the histopathological and immunohistochemical examination is decisive for establishing the diagnosis with certainty.*

*Case presentation: We present the case of a 33-year-old patient who presented to the Hematology Department in December 2023, complaining of physical asthenia, significant weight loss, and generalized lymphadenopathy, most of which were fistulized. A CT scan at that time revealed multiple cavitary images in the upper right pulmonary lobe, necrotic lymph node masses at the cervical, thoracic, and abdominal levels, the presence of a tracheoesophageal fistulous tract, pericardial fluid exerting mass effect on the heart, as well as secondary pulmonary, splenic, and bone lesions. A lymph node biopsy was performed, and the HP+IHC examination was compatible with classical HL – nodular sclerosis subtype. Considering the cavitary pulmonary lesions, a Pulmonology consult was requested, which recommended initiating antituberculous treatment. In parallel, A-AVD therapy was initiated according to national guidelines, and pericardial drainage was performed. A PET-CT evaluation after 3 cycles showed the disappearance of subdiaphragmatic lymphadenopathy, but persistence of supradiaphragmatic lymphadenopathy and pulmonary lesions with increased metabolic activity – Deauville 4. Treatment was continued with another 3 cycles, and imaging evaluation revealed both dimensional and metabolic regression of the supradiaphragmatic lymphadenopathy – Deauville 2. Complete remission was achieved, and the patient has been monitored periodically at 3-month intervals (PET-CT, August 2025, Deauville 2), necessitating esophagoplasty.*

*Conclusion: In Hodgkin's lymphoma, the immunosuppression associated with the disease favors the occurrence of infections, including pulmonary tuberculosis.*

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# Study on Monoclonal Gammopathies Treated in the Arad Hematology Clinic During the Year 2025

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*Monoclonal gammopathies - group of diseases defined by monoclonal plasmacytic proliferation. Multiple myeloma: plasmacytic neoplasm, representing 1%-1.8% of all neoplasms, incidence in Europe is of approximately 4.5 per 100,000 population/year.*

*Purpose: Outlining an overview of patients with plasmacytic dyscrasias undergoing treatment during 2025 from the perspective of associated pathologies, complications, stage evaluation of treatment effectiveness.*

*Methodology: Cases of monoclonal gammopathies treated in the Arad Hematology Clinic during 01.01.2025-31.08.2025 were studied. The following aspects were analyzed from the clinical observation sheets: distribution of cases by age group, sex, comorbidities, line of treatment, complications; number of cases - 30 patients. Results and discussions: women between 40 - 89 years old predominate, men between 70-79 years old. Cardiac and renal comorbidities are the most common. IgG Multiple Myeloma was the most common pathology observed. 66.66% of patients show a positive response to treatment, the rest are under evaluation. Transplanted patients - 10%, 2 patients are eligible for transplatation. The main post-therapy complications are anemia and thrombocytopenia.*

*Conclusions: Daratumumab-based treatment regimens show increased efficiency in inducing remission, except patients with high genetic risk. The continuous development of new therapies gives an increasingly optimistic perspective on the poor prognosis of this disease.*

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# GATA2 Deficiency Syndrome

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*GATA2 Deficiency Syndrome is a rare hematopoietic disorder, either inherited or de novo, caused by pathogenic variants in the GATA2 gene. It is associated with recurrent severe infections, cytopenias and an increased risk of myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML). Early recognition is essential, but diagnosis is often delayed due to the heterogeneous clinical presentation.*

*We report the case of a 32-year-old female patient who presented to the hospital with general weakness and menometrorrhagia. Relevant medical history includes persistent cytopenias since early adulthood, recurrent cutaneous and genital infections, chronic arthralgia and hearing loss. Laboratory evaluation revealed a myelodysplastic syndrome, which later progressed to leukemia. In light of the clinical presentation, next-generation sequencing (NGS) was performed and identified a mutation in the GATA2 gene, with a variant allele frequency of ~50%, supporting the suspicion of GATA2 deficiency syndrome.*

*This case highlights the diagnostic challenges of GATA2 deficiency and emphasizes the importance of genetic testing in patients with persistent cytopenias of unknown cause and recurrent infections. Reporting individual cases contributes to a better understanding of the diverse clinical spectrum of GATA2 deficiency and may facilitate earlier diagnosis and intervention.*

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# Risk Stratification in Chronic Myeloid Leukemia: Clinical Relevance of Elts Compared to Sokal and Hasford Scores

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*Objective: Accurate risk stratification in chronic myeloid leukemia (CML) is critical for optimizing treatment selection and improving long-term outcomes. This study aimed to evaluate the clinical relevance of Sokal, Hasford, and ELTS prognostic scores, determine which model most accurately predicts treatment response, and assess the impact of discordant risk classifications in patients diagnosed and treated between 2020 and 2025.*

*Materials and Methods: We conducted a retrospective analysis of 15 patients treated in the Hematology I Department, Colentina Clinical Hospital. Sokal, Hasford, and ELTS scores were recalculated to ensure accuracy. Patient records were reviewed, and responses to first- and subsequent-line tyrosine kinase inhibitor (TKI) therapy were analyzed in relation to prognostic categories.*

*Results: Among the 15 patients, 4 (26.6%) were consistently low risk across all three scoring systems and achieved sustained responses to first-line TKI therapy. One patient (6.6%) was high risk in all systems and has maintained a deep molecular response on second-line therapy for over two years. The remaining 10 patients (66.6%) exhibited discordant classifications, with ELTS frequently assigning a higher risk than Sokal and Hasford. Notably, patients identified as intermediate risk by ELTS but low risk by the older models often failed first-line therapy and required transition to second-line treatment, with one patient currently on fourth-line therapy.*

*Conclusion: ELTS demonstrates superior prognostic accuracy in predicting treatment failure and long-term outcomes. In cases of score discordance, ELTS should be prioritized to guide risk-adapted therapeutic strategies, improve treatment selection, and support individualized long-term management in CML.*

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# From Metastatic Seminoma to Secondary Acute Myeloid Leukemia: A Dual Hemato-Oncologic Challenge

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*Objective:* We present a rare case of acute myeloid leukemia (AML) secondary to a young patient, arising after multimodal treatment of metastatic testicular seminoma, highlighting the associated diagnostic, therapeutic, and genetic challenges.

*Materials and methods:* A retrospective analysis of clinical and paraclinical data (peripheral blood smear; bone marrow aspirate, molecular biology, cytogenetics, imaging studies, HLA typing).

*Results:* We present the case of a 24-year-old patient diagnosed in 2022 with metastatic testicular seminoma, treated with radical orchiectomy, BEP chemotherapy (Bleomycin, Etoposide, Cisplatin), repeated administration of zoledronic acid, followed by radiotherapy, achieving partial remission in 2023.

In 2024, the patient developed persistent pancytopenia, initially suspected to be a secondary myelodysplastic syndrome following chemotherapy. In August 2025, the peripheral blood smear showed 39% blasts, and bone marrow aspirate 87%, confirming AML FAB type 1. Molecular biology identified the MYH11 fusion type D, associated with favorable prognosis, but cytogenetics revealed complex abnormalities including hypertriploidy (65–79 chromosomes), hypertetraploidy (83–88 chromosomes), multiple tetrasomies, trisomies, marker chromosomes – defining an overall unfavorable risk.

Induction therapy 7+3 (cytarabine + anthracycline) was initiated, and HLA typing for allogeneic transplant showed partial compatibility (6/10) in one sibling and complete incompatibility in the other, with the transplant center set to decide between haploidentical transplant and unrelated donor.

*Conclusions:* This case highlights the complexity of secondary leukemias in the context of germ cell tumor treatment, emphasizing the importance of long-term monitoring and rapid intervention to identify a curative strategy. The contradictory genetic profile and young age make the situation both challenging and relevant for hematologic and oncologic practice.

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# **Race Against Time: Acute Myeloblastic Leukemia, Invasive Fungal Infection and Transfusional Inefficiency - A Clinical Case with Unpredictable Evolution**

**Adela-Sara Ionescu, Mihaela-Sabrina Herdea, Geanina Carla Ofițeru, Mihaela Andreescu**

*Aim: The aim of this paper is to highlight the diagnostic and therapeutic challenges in a complex clinical case, with an unpredictable course due to infectious and immunological complications.*

*Material and method: A 49-year-old female patient, with a history of thyroid nodule and benign tumor of left lower limb, was diagnosed with acute myeloblastic leukemia (AML), FAB M5, FLT3 positive (bone marrow cytology revealed 82% large blasts, suggestive of AML; immunophenotyping supported the diagnosis; molecular analysis confirmed the presence of FLT3-ITD; cytogenetic testing showed monosomies not classified as a clone). Induction chemotherapy was initiated with Idarubicin, Cytarabine ('3+7'), and Midostaurin (days 8-21).*

*The patient's course was marked by major complications during the aplastic phase: platelet transfusion refractoriness (multiple anti-HLA antibodies were identified, requiring administration of selected blood products) and sepsis of digestive origin with lingual mycological examination, blood cultures, and urine fungal culture all positive for *Saprochaete capitata*.*

*Results: CT imaging raised a strong suspicion of rectal proliferative process, which was subsequently ruled out by colonoscopy (benign sigmoid polyp). Given the persistent inflammatory syndrome, an abdominal MRI was performed, revealing hepatic and splenic micronodules (leukemic implants versus microabscesses in context of sepsis). Liver biopsy confirmed a suppurative inflammatory process consistent with hepatic abscess.*

*From a hematological perspective, the patient achieved complete remission at the end of induction chemotherapy (bone marrow cytology showing 2-3% blasts).*

*Conclusions: The clinical outcome remains uncertain and is influenced by the management of the invasive fungal infection. Nevertheless, this case is particularly relevant to current clinical practice.*

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# Management of CLL Patients - Real-World Evidence from a Single Centre Study

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*Introduction: Chronic lymphocytic leukemia (CLL) is an indolent but heterogeneous lymphoproliferative disorder. Real-world data are essential to complement information from clinical trials and to guide therapeutic decisions.*

*Methods: We performed a retrospective study on 112 patients with CLL treated at Colentina Clinical Hospital, Bucharest, between January 2009 and June 2025. Data analyzed included Binet stage, Charlson Comorbidity Index (CCI), and cytogenetic/molecular markers. Main endpoints were time to first treatment (TTFT), treatment patterns, and response rates. Statistical analyses used Mann-Whitney U and Fisher's exact tests, with  $p < 0.05$  considered significant.*

*Results: Median age was 65 years, with male predominance (58%). Distribution by Binet stage was: A 43.8%, B 42.0%, C 14.3%. Half of the patients remained in "watch and wait," while 50% initiated therapy, with a median TTFT of 2.2 months. The most frequent first-line regimens were Obinutuzumab–Venetoclax (25.5%), Acalabrutinib (21.8%), and Ibrutinib–Venetoclax (14.5%). Complete response was achieved in 70.9% of treated patients. The need for therapy correlated strongly with Binet stage ( $p < 0.001$ ). Among patients with unmutated IGHV, 91.3% required treatment, while 75% of those with high-risk cytogenetic/molecular abnormalities required earlier therapy. A CCI score  $> 4$  was associated with a 21.1% increased risk of death ( $p = 0.005$ ).*

*Conclusions: This real-world study confirms the prognostic value of Binet stage as a major predictor of treatment initiation. Molecular markers and comorbidities also influenced outcomes, emphasizing the importance of risk-adapted, personalized strategies. Validation through prospective studies on larger cohorts is needed to optimize management and improve survival in CLL.*

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# Multidisciplinary Management of Severe Infectious Complications in Acute Myelomonocytic Leukemia

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*Objective: To present the clinical, diagnostic, and therapeutic particularities of a case of Acute Myelomonocytic Leukemia (AML), emphasizing infectious and surgical complications, and the multidisciplinary approach.*

*Methods: Description of the particularities of a multidisciplinary managed case involving detailed clinical evaluation, immunophenotyping, cytogenetic examination, molecular biology and monitoring of therapeutic response. The clinical evolution and complications during polychemotherapy treatment were analyzed.*

*Results: A 56-year-old female patient with 17 years of toxic exposure and grade II hypertension presented with asthenia and fatigue. On admission to Hematology Clinic, hepatosplenomegaly, severe anemia, severe thrombocytopenia, and marked leukocytosis were identified. AML diagnosis was established, and "3+7" chemotherapy with Cytarabine and Idarubicin was initiated. Multidrug-resistant *Klebsiella pneumoniae* infection was confirmed, requiring treatment with Zavicefta and Aztreonam. Subsequently, the patient developed phlebitis in the right upper limb, necessitating multiple surgical consultations and transfer to the Oncological Surgery Clinic for debridement and negative pressure wound therapy. Local culture confirmed recurrent *Klebsiella* infection; Emblaveo treatment was administered. After infection control and wound healing with skin grafting, a complete clinical response was achieved, and the second cycle of "3+7" chemotherapy was continued, with preparation for allogeneic transplant from a related donor.*

*Conclusions: This case highlights the complexity of AML management amid severe infections. Multidisciplinary collaboration, tailored surgery, and targeted antibiotic therapy enabled complication control and continuation of hematologic treatment, underscoring the importance of integrated personalized approaches for optimizing clinical outcomes.*

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# Acute Myeloid Leukemias Associated with DEK-NUP214 and FLT3-ITD Mutations – A Case Series

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*Introduction: Acute myeloid leukemia (AML) is a heterogeneous malignant hematologic disorder in which the genetic profile plays a crucial role in determining prognosis and guiding therapeutic strategies. The translocation t (6;9)(p23;q34), which leads to the DEK-NUP214 gene fusion, and mutations in the FLT3 gene, particularly FLT3-ITD, are molecular alterations associated with aggressive forms of the disease, poor response to chemotherapy, a high risk of relapse, and reduced overall survival.*

*Materials and methods: A retrospective analysis was conducted on four clinical cases diagnosed with AML at the Hematology Clinic of the Clinical Institute Fundeni, all presenting FLT3-ITD mutations and/or the DEK-NUP214 translocation. The analysis included two female patients aged 40 and 43, and two male patients aged 41 and 51. For each case, clinical and biological characteristics, genetic profile, immunophenotyping, molecular biology, administered treatments, and short- and long-term outcomes were evaluated.*

*Results: All four patients were diagnosed with AML exhibiting genetic profiles classified by ELN as adverse-risk: one case showed the DEK-NUP214 translocation, while the remaining three also had associated the FLT3-ITD mutation. The response to induction chemotherapy was suboptimal in all cases, with rapid unfavorable progression. Only one patient survived, while the other three died during the course of the disease, despite intensified treatment efforts. For these patients, the curative therapeutic approach remains allogeneic stem cell transplantation in first complete remission.*

*Conclusions: The presence of FLT3-ITD mutations and DEK-NUP214 translocation in AML is associated with an adverse prognosis, characterized by treatment resistance and short survival. The analyzed cases confirm the current literature regarding the aggressiveness of these AML subtypes. These observations underscore the importance of early molecular diagnosis and the need for personalized therapeutic approaches, including targeted therapies and early stem cell transplantation where feasible.*

*Keywords: acute myeloid leukemia, DEK-NUP214 mutation, FLT3-ITD mutation, chemotherapy*

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# A Challenging Triad: Coexisting Hereditary Hemochromatosis, Porphyria and Hemophilia In a Single Patient. Case Presentation and Comprehensive Review

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*Rare hematologic and metabolic disorders such as thalassemia, porphyria, and hemochromatosis remain underdiagnosed and underreported, despite their significant clinical impact. These conditions involve complex interactions between genetic, hematologic, and metabolic pathways, posing challenges for accurate diagnosis and effective management.*

*The medical literature describes associations between hereditary hemochromatosis and porphyria cutanea tarda, as well as cases linking beta-thalassemia (minor or major) with porphyria cutanea tarda; however, no reports have documented the coexistence of all three conditions in the same patient.*

*This review aims to provide a comprehensive overview of thalassemia, porphyria, and hemochromatosis, highlighting their clinical overlap, key distinguishing features and implications for diagnosis and personalized management, while illustrating these concepts through a representative clinical case.*

*In this context, we report the case of a 37-year-old male patient diagnosed with porphyria cutanea tarda, beta-thalassemia minor, and hemochromatosis.*

**Keywords:** beta-thalassemia minor; Porphyria cutanea tarda, hemochromatosis, rare hematologic disorders, rare metabolic disorders

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# Primary Cerebral Diffuse Large B-Cell Lymphoma

**B. Marin, Alexandra Liboteanu, Cristina Potre, O. Potre, Ema Borsi, Ioana Ionita**

*Objective: Presentation of a clinical case of diffuse large B-cell non-Hodgkin lymphoma with primary cerebral involvement, with a chronological analysis of the clinical course and therapeutic strategies applied.*

*Materials and methods: The analysis consisted of a retrospective evaluation of clinical, imaging, and histopathological data, correlated with the therapeutic management of a 68-year-old male patient, diagnosed and treated at the Hematology Clinic of Timisoara between February and May 2025.*

*Results: The patient initially presented with confusional syndrome and aphasia. Cranial MRI examination revealed a left frontal expansile process. The tumoral mass was surgically excised in December 2024, and subsequent histopathological and immunohistochemical analysis established the diagnosis of high-grade diffuse large B-cell non-Hodgkin lymphoma. The patient was later admitted to the Hematology Clinic in Timisoara, where, on February 21, 2025, the first cycle of R-MAA immunochemotherapy was initiated. The regimen was relatively well tolerated, with partial improvement of neurological symptoms; however, severe neutropenia and thrombocytopenia occurred, requiring treatment with granulocyte colony-stimulating factor and platelet transfusions. After three cycles, a complete clinical, biological, and radiological response was achieved, with the normalization of hematologic parameters and the near-complete remission of neurological signs. Notably, during the third cycle, Methotrexate was withheld and the Cytarabine dose adjusted due to impaired renal function.*

*Conclusions: Primary cerebral diffuse large B-cell non-Hodgkin lymphoma is a rare entity with aggressive progression if untreated. Prompt initiation of therapy, despite immediate and delayed risks, was decisive for patient recovery and long-term survival.*

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# **Hemolytic Anemia Due to Maternal-Fetal Incompatibility in the RH System, A Frequent Cause of Apnea of Prematurity**

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*Objective: The application of general and special prophylaxis norms regarding RH isoimmunization, the inclusion of ABO and RH blood group phenotyping in the premarital examination, as well as performing the indirect Coombs test in RH-negative women of childbearing age, are important elements in maintaining general health.*

*Material and methods: The study was conducted on premature newborns registered at the Filantropia Municipal Clinical Hospital in Craiova who developed apnea crises and required the administration of methylxanthines. The presence of anti-RH antibodies fixed on the red blood cells of newborns with hemolytic anemia was demonstrated by a positive direct Coombs test.*

*Results: Hepato-splenomegaly secondary to intense hemolysis led to an increase in the volume of the fetal abdomen. Due to extramedullary hematopoiesis, the liver's protein-forming function diminished, with the onset of hypoalbuminemia, alteration of colloid osmotic pressure, plasma extravasation and the appearance of edema. Hemolysis led to the accumulation of large amounts of bilirubin with the onset of severe jaundice in the newborn. Histopathological examination of the placenta revealed dystrophic villi, fibrinoid necrosis and calcareous deposits, areas of recent and old infarction, as well as umbilical vein microthrombosis.*

*Conclusions: Special prophylaxis of RH isoimmunization consists of administering 300 micrograms of anti-D immunoglobulin to RH-negative pregnant women with RH-positive husbands, who are not immunosuppressed, between weeks 28-30 of gestation, and a new administration within the first 72 hours of birth only if the newborn is RH-positive, the life of these antibodies being approximately 12 weeks.*

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# Acute Myeloid Leukemia with FLT3-ITD in an Elderly Patient: Prognostic Implications and Challenges in Infection Management

**B. Nistor, E. Pirvu, I. Marian, S. Herdea, S. Ionescu, G. Ofiteru, V. Popov, M. Andreescu**

*Objective: To highlight the diagnostic challenges and severe infectious complications that occurred during induction therapy in an elderly patient with acute myeloid leukemia (AML) carrying the FLT3-ITD mutation.*

*Materials and methods: The paper presents the case of a 69-year-old patient under the care of the Hematology Department of Colentina Clinical Hospital. Diagnostic evaluation included cytological examination, immunophenotyping, cytogenetic analysis, and molecular testing.*

*Results: The patient was initially admitted with suspected acute promyelocytic leukemia. Further investigations established the diagnosis of AML with minimal differentiation, FLT3-ITD positive, without the t(15;17) translocation. Induction chemotherapy with the "3+7" regimen (cytarabine + idarubicin) was initiated, with multidisciplinary monitoring. The clinical course was complicated by profound bone marrow aplasia and severe infections, including metapneumovirus-associated bronchopneumonia, suspected pneumocystosis, and infectious colitis. The situation required transfer to the ICU, where complex life support and broad-spectrum antibiotic and antifungal therapy were administered. After recovery and documentation of complete remission, maintenance therapy with oral azacitidine was initiated, which has been well tolerated to date.*

*Conclusions: This case highlights the complexity of the differential diagnosis between AML and APL, as well as the vulnerability of elderly, immunocompromised patients facing severe infectious complications during intensive therapy. Identification of the FLT3-ITD mutation has major prognostic value; however, therapeutic options were limited by treatment toxicity and the high risk of infections. A multidisciplinary approach and individualized consolidation and maintenance strategy enabled the achievement of hematological remission and the preservation of an optimized quality of life in the clinical context.*

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# Immune Restoration in Patients with Chronic Lymphocytic Leukemia Treated with Bruton's Tyrosine Kinase Inhibitors: Data from a Small Center

**Ana-Maria Petraru, Diana Malenda, Mihaela-Sabrina Herdea, Diana Drăgoi-Cozmaciuc, Viola Popov, Mihaela Andreescu**

*Aim: To assess the status of humoral immunity, the incidence of infections, and the need for immunoglobulin substitution in patients with chronic lymphocytic leukemia (CLL) receiving Bruton's tyrosine kinase inhibitors (BTKi), based on the experience of a small center.*

*Material and methods: Sixteen patients with CLL under follow-up in the Hematology I Department, Colentina Clinical Hospital, treated with BTKi (Ibrutinib and Acalabrutinib), who had at least one immunogram assessment during therapy, were included in the analysis. Data were collected from the hospital's electronic medical system and by interviewing patients regarding their infection history.*

*Results: The median age of patients included in the analysis was 72.6 years. The median treatment duration with Ibrutinib was 41.5 months, while for Acalabrutinib it was 12 months. The median serum immunoglobulin G (IgG) level was 639 mg/dL, and 25% of patients required immunoglobulin substitution (IgG <400 mg/dL or <600 mg/dL associated with infections). Only 18.8% of patients actually received subcutaneous immunoglobulin substitution. The overall infection rate in the cohort was 25%.*

*Conclusions: The relative stability of IgG levels during therapy and the modest infection rate suggest the possibility of immune restoration under BTKi. Although limited by sample size, these findings warrant replication and highlight the need for long-term monitoring of immunograms to better define the impact of BTKi on humoral immunity.*

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# The Relevance of TBNK Profiling for Immune Response Monitoring in Multiple Sclerosis Patients

Codruța Popa<sup>1,2</sup>, T. Tudor<sup>1</sup>

*Aim: Multiple sclerosis (MS) is a chronic inflammatory disease of the central nervous system, characterized by demyelination and neurodegeneration, in which T, B, and NK lymphocytes play central roles. Ocrelizumab, an anti-CD20 monoclonal antibody used as background therapy, induces profound B-cell depletion and modulates immune homeostasis. This study aimed to assess TBNK immunological changes induced by treatment, analyzed by age group using flow cytometry.*

*Material and methods: Between 2023 and 2025, 62 participants were included: 42 patients with relapsing-remitting MS treated with ocrelizumab and 20 healthy individuals (control). Patients were monitored in seven visits at three-month intervals. For statistical analysis, visits V3–V5 were selected as representative of pharmacodynamic stability. Immunophenotyping was performed by multiparametric flow cytometry using a standardized TBNK panel.*

*Results: A 93% reduction of CD19<sup>+</sup>/CD20<sup>+</sup> B cells was observed compared with controls. In the T-cell compartment, the 16–30 years group showed a 35.6% decrease in total T cells, with a stable CD4/CD8 ratio (+6.5%). In the >45 years group, the overall reduction was similar (–36.2%) but associated with a disproportionate decline of CD8<sup>+</sup> (–26.8%) and an increase of CD4<sup>+</sup> (+11.6%), resulting in a marked rise of the CD4/CD8 ratio (+56%). NK cells decreased by 26% in the 16–30 years group and increased by 28% in the >45 years group.*

*Conclusions: Ocrelizumab significantly remodels the T, B, and NK compartments, with distinct age-related patterns. TBNK monitoring by flow cytometry is a useful tool for assessing immune response and for defining translational biomarkers that may support personalized therapeutic and prophylactic strategies in MS.*

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# Evolution of Plasmacytoma to Multiple Myeloma and Challenges in Treatment of a Patient with End Stage Chronic Renal Disease

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*Plasmacytoma is a rare malignancy affecting plasma cells in bony or soft tissue, evolving as solitary or multiple masses and progressing to multiple myeloma if untreated. Its low incidence (<450 cases/year in the US) and absence of systemic symptoms contribute to underdiagnosis and progression to multiple myeloma (20-60% within 3 years). We present the case of a 67-year-old male patient with chronic right sacroiliac joint pain, unresponsive to analgesics or balneotherapy. History includes chronic ischemic cardiomyopathy and stage 3 hypertension. Bloodwork reveals anemia, lymphopenia, and mild kidney dysfunction. Contrast-enhanced MRI and TAP CT highlight large expansile sacral mass affecting sacroiliac joint, associating bone lysis, medullary canal infiltration, and nerve fibre entrapment. Biopsy confirms solitary plasmacytoma diagnosis, likely due to long-term chemical exposure as a carpenter. Upon admission to Hematology, the patient exhibits worsening of hematologic conditions and acute renal failure. He is transferred to Nephrology and treated with blood transfusions, urinary catheter, and started on bortezomib and dexamethasone. During hospitalization E. coli sepsis develops with hepatocytolysis and cholestasis complications caused by Ciprofloxacin. Despite symptom improvement, bloodwork reveals renal dysfunction, leading to 5D stage chronic kidney disease diagnosis. Hemodialysis is initiated. These conditions confirm R-ISS3 IgG lambda multiple myeloma diagnosis. After kidney function regain, chemotherapy with CyBOR-D-III was initiated, later switched to daratumumab-bortezomib-dexamethasone (Dara/VRd) adapted for dialysis. Plasmacytoma, due to its rarity and non-specific symptoms, is challenging to diagnose and can rapidly progress to multiple myeloma. Renal impairment complicates treatment, emphasizing the need for research on chemotherapy impact on kidney function.*

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# Long-Term Management of Chronic Myeloid Leukemia

**Rafaela Stoianof, Mariana Vasilica**

*Introduction: Chronic myeloid leukaemia (CML) is a malignant haemopathy defined by translocation  $t(9;22)$  and BCR-ABL fusion. The introduction of tyrosine kinase inhibitors (TKIs) has transformed the prognosis, with most patients achieving deep molecular remissions and survival close to the general population. However, up to 30% of patients require changing TKI due to resistance or intolerance, which makes long-term management a challenge.*

*Case Presentation: We report the case of a 54-year-old patient diagnosed with CML in 2003, initially treated with imatinib and subsequently with dasatinib since 2019. The course was complicated by massive pleural effusion and persistent hydropneumothorax, a specific adverse reaction to dasatinib, with an incidence of up to 28%. The exact mechanism of dasatinib-induced pleural effusion is not fully elucidated but is assumed to involve both immunologic reactions and off-target effects on SRC and PDGFR $\beta$  kinases, increasing vascular permeability. After discontinuation of therapy and multiple episodes of drainage and symptomatic treatment, asciminib was initiated, achieving deep molecular remission (MR4). Currently, the patient is in a stationary clinical condition, with pleurisy in slow regression.*

*Conclusions: This case confirms literature data, including Jain et al. (2024), which reported pleural effusions in 17.6% of patients treated with dasatinib. The results support the use of asciminib in second-generation TKI intolerance and emphasize the importance of personalized treatment and continuous monitoring.*

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# The Gut Microbiome in Chronic Myeloproliferative Neoplasms: A Synthesis of Recent Literature

Laura-Gabriela Țîrlea<sup>1,2</sup>, Alina Daniela Tănase<sup>2,3</sup>, Mihaela Andreescu<sup>1,4</sup>

*Background and Objective:* Chronic myeloproliferative neoplasms (MPN) are clonal hematopoietic disorders marked by chronic inflammation. The gut microbiome, a key regulator of host immunity and metabolism, is increasingly investigated as an extrinsic factor influencing MPN evolution. This review aimed to synthesize recent evidence (2020–2025) on the microbiome–MPN relationship.

*Methods:* A PubMed search (2020–2025) was performed using the keywords “myeloproliferative diseases” and “gut microbiota.” Observational studies and relevant review articles on MPN were included. We analyzed differences in microbial composition, correlations with driver mutations, and clinical implications (transplant, diet, and microbiome-targeted interventions).

*Results:* Metagenomic studies reveal intestinal dysbiosis in MPN patients compared with healthy controls: reduced microbial diversity, decreased immunoregulatory taxa (e.g., *Faecalibacterium*), and pro-inflammatory taxa expansion (e.g., *Prevotella*). Distinct microbial profiles were reported in polycythemia vera and essential thrombocythemia, while *JAK2V617F* mutation correlated with more pronounced deviations than *CALR*-positive cases. Circulating microbiome signatures, identified in extracellular vesicles, also differed in MPN patients. In the allo-HSCT setting, severe dysbiosis was associated with higher rates of GvHD and mortality. Interventions such as fecal microbiota transplantation and specific dietary approaches indicated potential anti-inflammatory benefits.

*Conclusions:* The 2020–2025 literature supports the involvement of the gut microbiome in the inflammatory landscape and progression of MPN, highlighting prognostic and therapeutic implications, particularly in transplantation. Further studies on larger cohorts, including in Romania, are warranted to evaluate microbiome modulation as an adjuvant therapeutic strategy, considering local dietary variability. A study on this topic will be carried out as part of the lead author’s doctoral thesis.

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# **Acute Myeloid Leukemia NPM1+ Associated with Uterine Myeloid Sarcoma, Atypical Debut with APL Mimicry and Infectious Pathology at Presentation- Diagnostic Difficulties**

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*Purpose: Acute myeloid leukemia (AML) NPM1+ represents a distinct entity, frequently associated with normal cytogenetics and favorable prognosis in the absence of other adverse mutations. In certain cases though the clinical and paraclinical presentation can appear as other forms of AML, especially APL variants, that imposes the initiation of treatment in an emergency setting due to the vital risk associated with severe coagulopathy.*

*Materials and methods: This paper reports the case of a 56 years old patient, that came to the emergency department with a severe hemorrhagic syndrome, severe leukocytosis and severe bicytopenia with signs of disseminated intravascular coagulation (DIC) highly suggestive of APL. The peripheral blood smear outlined blasts with specific morphology – cup like cells- suggestive for AML NPM1+. Immunophenotyping exam confirmed the myeloid lineage SSC medium/high cMPO+, CD34 -, HLA-DR-, CD117+, CD33+ , CD64+ CD15+/-, CD9-, CD56- and molecular testing identified NPM1 mutation, PML-RARA negative. Imaging exams showed the presence of a tumor localized in the uterus, the biopsy confirming extramedullary involvement – myeloid sarcoma- with the same phenotyping profile. Additionally at the diagnosis the patient had multiple infectious complications (flu type A, and E. coli faringoamigdalitis).*

*Conclusion: This atypical clinical presentation AML NPM1 positive with APL like coagulopathy and myeloid sarcoma outlines the challenges in differential diagnosis for acute leukemias accompanied at diagnosis with coagulopathies, and the importance of integrating morphology, immunophenotype and molecular data for avoiding therapeutical errors in a context of hematological emergency.*

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# Peripheral T-Cell Lymphoma of Panniculitis-Like Type

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*Objective:* To present the clinical, diagnostic, and therapeutic particularities of a rare case of peripheral T-cell lymphoma of panniculitis-like type, highlighting infectious complications and the multidisciplinary approach.

*Methods:* Case presentation with clinical, histopathological, immunohistochemical evaluation, and therapeutic response monitoring. Analysis of clinical evolution and complications during polychemotherapy treatment.

*Results:* A 32-year-old female patient, with no significant prior medical history, presented with multiple subcutaneous infiltrates of varying sizes (2–5cm) in the inguinal, gluteal, and back regions. In the right gluteal area, a massive infiltrate (~15/10cm) was present with skin defect, associated with signs of tissue destruction and superinfection, for which multiple surgical interventions were performed, with no therapeutic success. Bacteriological examination of the wound revealed infection with multidrug-resistant *Pseudomonas aeruginosa*. Biopsy of the infiltrate confirmed the diagnosis of peripheral T-cell lymphoma of panniculitis-like type. A decision was made to initiate specific treatment with CHOEP, broad-spectrum antibacterial therapy, and surgical treatment of the wound (debridement + vacuum therapy). The treatment was complicated by severe neutropenia followed by sepsis and septic shock, requiring complex therapeutic interventions. After general condition stabilization, specific therapy was continued, the tissue defect was covered with artificial dermis and a VAC device. After 6 treatment cycles, complete clinical response was obtained (negative PET-CT), with normalization of hematologic parameters, resolution of infiltrates, and wound healing.

*Conclusions:* Panniculitis-like T-cell lymphoma is a rare entity with aggressive clinical course. Diagnosis requires biopsy and complete immunohistochemical evaluation. Initiating specific therapy, despite the existing risks, was decisive for the patient's recovery. Multidisciplinary management and adaptation of therapy to complications were essential for the successful resolution of this case.

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# Carfilzomib in Relapsed Multiple Myeloma: Response Patterns in Early Biologic Versus Clinically Aggressive Relapse

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*Scope: Relapsed multiple myeloma (MM) can present either as a biologic relapse or as a clinical relapse. While real-world studies have characterized outcomes of carfilzomib-based regimens in relapsed/refractory multiple myeloma, data comparing efficacy in biologic versus clinical relapse presentations remain limited.*

*Material and method: We retrospectively reviewed 7 patients with relapsed/refractory MM treated with carfilzomib-based combinations at our center; diagnosed between 2013–2025. Patients were categorized at relapse as having either biologic progression (n=3) or clinical relapse with CRAB features (n=4). Clinical outcomes, responses, tolerability, and complications were assessed.*

*Results:*

- *Biologic relapse group: Patients relapsed with rising monoclonal protein and/or marrow infiltration without end-organ damage. Carfilzomib-based regimens achieved rapid disease control and were well tolerated. Two patients remain on therapy with sustained remission beyond 12 cycles, while one achieved partial response before therapy modification due to toxicity.*
- *Clinical relapse group: Patients presented with anemia, renal dysfunction, lytic bone lesions, or pathological bone fracture. Carfilzomib therapy achieved initial disease control in all cases. However, this group showed higher rates of treatment-related complications (pulmonary infections, sepsis, or renal decline). Two patients discontinued therapy due to infectious complications.*

*Conclusion: Carfilzomib-based regimens demonstrated efficacy in both biologic and clinical relapses of MM, supporting their role as effective salvage options. Patients with biologic relapse achieved sustained responses with fewer complications, while those with clinical relapse derived benefit but faced higher comorbidity-related risks. These findings highlight the importance of early intervention at biologic relapse, before irreversible organ damage, to maximize therapeutic outcomes with carfilzomib.*

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# Transfusional Particularities in Patients with Multiple Myeloma

**M.G. Zaides, Andreea-Cristiana Vasile, Mihaela-Sabrina Herdea, Diana Grasu, Oana Patrinoiu, Mihaela Andreescu, Viola Popov**

*Background:* In multiple myeloma, transfusion requirements represent a major consequence of bone marrow infiltration and therapy-induced myelosuppression. Current literature reports that regimens containing Carfilzomib and Daratumumab, although improving overall survival and treatment response, are frequently associated with severe anemia and thrombocytopenia, requiring repeated transfusional support.

*Aim:* To evaluate the need for transfusional replacement therapy in patients with multiple myeloma undergoing treatment with Carfilzomib or Daratumumab.

*Material and method:* A retrospective study was conducted between 2023–2025 in the Department of Hematology I, Colentina Clinical Hospital, including 25 patients who were at least in the second therapeutic line involving Daratumumab or Carfilzomib. Clinical and biological data, administered protocols, adverse events, and transfusion requirements were collected from medical records, with patients' informed consent.

*Results:* Five patients (20%) presented with anemia ( $Hb < 8$  g/dL) and/or severe thrombocytopenia ( $PLT < 10,000/mm^3$ ) requiring transfusional support, while two patients (8%) required blood product substitution more than once per month. Five patients (20%) received the DaraKD regimen, and transfusional requirements were compared with other Daratumumab-based regimens (DaraPomDex, DaraRD, DaraVD).

*Conclusions:* These cases highlight the significant impact of modern anti-myeloma therapies on hematopoiesis, with increased transfusion requirements that mandate close monitoring and proactive planning of supportive resources.

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