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METHOD COMPARISON OF A NOVEL SLIDE-BASED INTEGRATED HEMATOLOGY ANALYZER AND A FLOW CYTOMETRY-BASED SYSTEM USING SAMPLES WITH TARGETED MEDICAL CONDITIONS

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Background: The **cobas m** 511 integrated hematology analyzer (**cobas m** 511 system) is a novel slide-based system that performs a CBC, WBC differential, reticulocyte count, and nucleated RBC count using digital analysis.
Aims: This single-center study investigated whether the **cobas m** 511 system delivered comparable results to the Sysmex® XN-10 Automated Hematology Analyzer using samples from patients with medical conditions.
Methods: Laboratory hematology results were reviewed to identify subjects with 23 targeted medical conditions (including hematological malignancies and disorders of cell numbers and function). Residual whole blood samples (n=130) were processed on both systems within 8 hours of venipuncture. Consistent with CLSI EP09-A3, a method comparison was used to assess the correlation and bias between the systems for all parameters. Individual patient parameter results that were valid on both instruments were included.
Results: All 26 reportable parameters evaluated showed good-to-excellent correlation between the automated results of the **cobas m** 511 system and Sysmex Analyzer, with no significant bias (**Table 1**).

Table 1. Cobas m 511 *vs* Sysmex Analyzer results.

Parameter [units]	Sample range	Pearson's R	Intercept	Slope
WBC [$10^3/\mu L$]	(0.11-95.41)	0.999	-0.02	0.995
RBC [$10^6/\mu L$]	(1.79-7.68)	0.996	-0.01	0.992
HGB [g/dL]	(6.28-17.24)	0.995	-0.31	1.064
HCT [%]	(18.60-56.00)	0.982	-0.53	1.034
MCV [fL]	(69.50-107.80)	0.879	5.35	0.975
MCH [pg]	(20.22-36.48)	0.977	2.87	0.946
MCHC [g/dL]	(28.20-36.42)	0.548	14.88	0.559
RDW [%]	(11.50-27.10)	0.929	2.81	0.850
RDW-SD [fL]	(34.10-93.00)	0.908	7.46	0.910
PLT [$10^3/\mu L$]	(9.00-1379.00)	0.994	-2.02	0.943
MPV [fL]	(8.40-13.00)	0.843	0.82	0.915
#NRBC [$10^3/\mu L$]	(0.00-4.44)	0.980	N/A	N/A
#NEUT [$10^3/\mu L$]	(0.46-36.82)	0.999	0.03	1.008
#LYMPH [$10^3/\mu L$]	(0.16-4.89)	0.985	0.01	0.976
#MONO [$10^3/\mu L$]	(0.14-7.65)	0.991	-0.03	1.013
#EO [$10^3/\mu L$]	(0.00-1.23)	0.978	0.00	1.031
#BASO [$10^3/\mu L$]	(0.00-2.51)	0.962	-0.08	1.829
#RET [$10^6/\mu L$]	(0.00-0.34)	0.971	-0.01	0.982
HGB-RET [pg]	(14.68-42.04)	0.934	-2.75	1.193

Data for%NRBC,%NEUT,%LYMPH,%MONO,%EO,%BASO, and%RET not shown

Summary/Conclusion: The **cobas m** 511 system and Sysmex Analyzer produce comparable results for samples with targeted medical conditions. This demonstrates the robustness of the **cobas m** 511 system when abnormal samples are encountered.

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ANALYSIS OF PERCENT IDENTITY OF IGHV MUTATION AS PROGNOSTIC FACTOR IN CLL PATIENTS TREATED WITH FLUDARABINE, CYCLOFOSFAMIDE AND RITUXIMAB: A SINGLE CENTRE EXPERIENCE

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Background: The mutation status of the immunoglobulin heavy chain variable region gene (IGHV) is an established prognostic factor in patients with chronic lymphocytic leukaemia (CLL). The degree of somatic hypermutation, determined as percent sequence identity to germline in IGHV (IGHV%) is analyzed in clinical practice. Currently CLL with<98% IGVH identity are considered "mutated" and CLL patients with >98% IGHV identity are considered "unmutated. " Recent data have assessed the prognostic role of IGHV% as a continuous variable in CLL patients treated with fludarabine, cyclophosphamide and rituximab (FCR).
Aims: In our study we investigated the prognostic significance of absolute percent identity of somatic of IGHV mutation on Progression Free Survival (PFS) and Overall Survival (OS) in unmutated CLL patients (pts) treated with frontline FCR in our Institution.
Methods: We retrospectively evaluated 73 pts with CLL treated with frontline FCR at the University Hospital of Bari (Italy) with a median of 5 years follow-up. The mutational status of the IGHV was studied in all pts and the degree of somatic hypermutation of IGHV was determined as percent identity from the germline sequence. Pts were divided in mutated and unmutated using a cut-off of 98% sequence identity. Among unmutated pts (identity sequence >98%) we selected two groups: the first one between 98% and 99% (IGHV-98-99%) and the second one with identity range between 99% and 100% (IGHV-99-100%), respectively. PFS and OS were calculate and compared between the two groups.
Results: Among the 73 CLL pts treated with frontline FCR 48 pts (65%) with unmutated IGHV CLL were identified; among them, 20 pts (41%) and 28 (59%) belonged to IGHV 98-99% and IGHV 99-100% group, respectively. No significant differences were observed (p=ns) in terms of PFS and OS between the two groups.
Summary/Conclusion: In our study no difference in terms of survival was observed in unmutated IGHV CLL pts on the basis of the percent identity of IGHV mutation for distinguishing two classes of risk. Further studies and more consistent cohorts of pts are warranted to confirm these data.

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DOES THE DOSE MODIFICATION OF FLUDARABINE, CYCLOPHOSPHAMIDE, RITUXIMAB (FCR) IMPACT TREATMENT OUTCOME IN PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA? ANSWER BASED ON SINGLE CENTER "REAL-LIFE" DATA

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Background: There are little published …real life" data about fludarabine, cyclophosphamide, and rituximab (FCR) combination in patients with chronic lymphocytic leukemia (CLL).
Aims: Herein, we present single-center experience based on long-term follow up of 170 CLL pts treated with FCR with focus on side effects and their impact on the outcome.
Methods: In this retrospective study, we analyzed data from 170 pts with CLL treated with FCR, mostly as a first-line treatment pointing at the correlation between side effects frequency, dosage, and treatment outcome.
Results: Median follow-up was 49 months (range, 2-180). Male/female ratio was 2.8:1 and median age before treatment commencement was 61 year, while 72% of pts were younger than 65 years. Unfavourable cytogenetic profile (del17p and/or del11q) carried 25% of patients. Most of the pts (72%) received FCR as a first-line treatment. Thirty-five percent of patients had a dose reduction of FC from the beginning (82%) or during the treatment (18%), most of them (87%) of >25% of the expected full dose. More than a half dose reductions were due to decreased creatinine clearance, in 18% the reason was neutropenia and/or infections, 13% physician's decision and 15% for other reasons. A hundred and ten (67%) pts completed their treatment with 6 FCR cycles, but only 72 (42%) pts received 6 cycles of full-dose FCR. Fifty-six percent of pts at least once received granulocyte colony-stimulating factor (GCSF) for neutropenia grade 3 or 4, 45% of pts had at least one episode of prolonged neutropenia, 16% exhibited late-onset neutropenia, while 28% of pts had infection that caused treatment delay and/or interruption, and/or hospitalization. Neutropenia occurrence was not related to sex, age, comorbidity status, leukocyte count, or cytogenetic profile, but it was significantly more frequent in pts who had already been treated with some chemotherapy regimen (p= 0.035). It occurred significantly more often in pts who did not complete their treatment with 6 cycles (67% *vs* 50%; p=0.046). Treatment delay was observed in almost half of pts (48%), mostly due to severe neutropenia and infections, and in 90% of pts, it happened for the first time after some of the first 4 cycles. Thirty-four percent of pts experienced treatment discontinuation, 60% of them due to cytopenia(s) and/or infections and 22% due to the resistant or progressive disease. The overall response rate was 70,6%, equally split between complete (CR) and partial response (PR). When observing untreated pts, CR was achieved in 46,6% in contrary to 10,9% of previously treated pts (p<0.001). In our group, cytogenetic profile predicted treatment response only in treatment-naïve pts (p<0.001 *vs* p=0.376 for previously treated). Pts who received 6 cycles of full-dose FCR experienced significantly better treatment response (p<0.001). Treatment delay had not been shown to change the outcome when we observed the whole group and pts with