

ASSOCIATION OF PROGNOSTIC FACTORS WITH OVERALL SURVIVAL IN MYELODYSPLASTIC SYNDROMES: A COHORT STUDY

ПОВРЗАНОСТ НА ПРОГНОСТИЧКИТЕ ФАКТОРИ СО ПРЕЖИВУВАЊЕТО КАЈ МИЕЛОДИСПЛАСТИЧНИТЕ СИНДРОМИ: СТУДИЈА НА КОХОРТА

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ABSTRACT

Background: Myelodysplastic syndromes (MDS) are heterogeneous disorders in terms of clinical presentation, laboratory findings and life expectancies. A lot of studies have been conducted to determine factors that can refine the prediction of prognosis in MDS.

Aim: Our aim was to evaluate which prognostic factors had an impact on overall survival (OS) in MDS.

Methods: we conducted retrospective cohort study of 154 adult patients (81 male, 73 female) with MDS who presented to the University Clinic of Hematology, Ss Cyril and Methodius University, Skopje, Macedonia, from January 2011 to June 2014. Data on demographics, FAB classification, treatment and outcome were collected.

Results: Age and gender had no influence on OS ($p=.80847$ and $p=.974895$, respectfully). Different FAB subtypes had an impact on OS ($p = .00757$). Bone marrow (BM) blast percentage correlated significantly with OS ($p= .028026$). Hemoglobin, platelet count and absolute neutrophil count (ANC) did not influence OS ($p=.179970$, $p= .386355$ and $p= .972602$, respectfully). Transfusion did not influence OS ($p= .445856$). Albumins had no impact on OS ($p=.559900$). Lactate dehydrogenase (LDH) and comorbidities influenced OS ($p= .018895$ and $p= .02278$, respectfully). Leukemic transformation was noticed in 7 (4.5%) patients. Mortality was 35.1%.

Conclusions: FAB subtypes, BM blast percentage, LDH and comorbidities are independent predictors on OS and should be considered for future revisions of International Prognostic Scoring System in order to refine the prediction of prognosis in MDS.

Key words: myelodysplastic syndromes, overall survival, prognostic factors

INTRODUCTION

Myelodysplastic syndromes (MDS) comprise a group of clonal hematopoietic stem-cell disorders, characterized by ineffective hematopoiesis and peripheral cytopenias, heterogeneous clinical presentation, laboratory findings and life expectancies ranging from a few months to several years.^{1,2} Disease characteristics and outcomes are defined by FAB and WHO classification. Prognosis is defined by IPSS and R-IPSS score.³ Overall survival (OS) is important for both the patients and their physicians. Accurate prediction of a patient's prognosis is useful

to define the risk posed by the disease. For that reason it is of great importance to know the impact of some prognostic factors on OS. Some of them are already included in IPSS and R-IPSS - BM blast cell count, peripheral cytopenias and cytogenetics. There are a lot of studies trying to define other prognostic factors: age^{4,5,6,7,8}, gender^{4,7,8}, FAB subtypes⁹, RBC transfusion dependence^{10,11}, ferritin^{12,13,14,15,16}, albumins¹⁸, LDH¹⁷, mutations^{19,20,21} and co-morbidities.¹ Diagnosis requires BM examination, cytogenetic and lately molecular studies. The consensual

minimum criteria for diagnosis are presence of erythroid, granulocyte or megakaryocyte dysplasia in 10% or more informative cells.²² The incidence of MDS increases with age.^{4,5,6,7,23} Age had a significant effect on OS - the older the age, the worse the prognosis. The impact of gender on OS was observed in several studies. The incidence of MDS is higher in males than in females (1.5 - 2 to 1). Males had worse prognosis.^{4,7} FAB subtypes can worsen prognosis in MDS, with differences among subtypes.⁹ BM blast count showed a significant predictive value on OS.²³ More than 5% blasts in BM were considered as a bad prognostic factor for OS.^{24,25} Cytopenias did not reach statistical significance in OS.²³ The occurrence of anemia (hemoglobin < 10 g/dl) or thrombocytopenia (platelets < 100×10⁹ /l) was associated with a higher risk for OS. A lower absolute neutrophil count (< 1.8×10⁹/l) did not significantly affect OS.⁷ Red blood cell (RBC) transfusions are commonly used therapy for symptomatic anemia. Transfusion dependence is defined by the MDS International Study Group (2000) as requiring transfusion of at least one RBC unit at 8 weeks for 4 months.⁹ Transfusion-dependent patients had shorter survival rate than those who received less than 18 units of blood over a period of 36 months.²⁶ Serum ferritin level ≥500 µg/l at diagnosis was a strong independent predictor of survival. Serum ferritin significantly correlated with OS in Chinese patients.¹² Lactate dehydrogenase (LDH) should be recognized as a prognostic factor in MDS.¹⁷ One German study pointed out the correlation between LDH level and OS.²¹ Serum albumin is an independent prognostic factor that influences OS.¹⁸ Recurrent chromosomal abnormalities have been identified in 40–70% of the 'de novo' MDS and 95% of secondary MDS. Favorable prognostic markers according to IPSS include: a normal karyotype, 5q- as an isolated anomaly, 20q- as an isolated anomaly and -Y chromosome. Karyotype findings associated with poor prognosis include complex karyotype and chromosome 7 abnormalities. Other cytogenetic abnormalities confer an intermediate prognosis.^{27,28} The abnormal karyotype correlates with poor prognosis and shorter OS.^{19,29} Somatic mutations are identified in more than 70% of MDS patients, including more of them with normal karyotype. They are major predictors of the clinical phenotype, and could also be predictors of prognosis.^{19,20,21} The incidence of MDS increases with age and so does the prevalence of co-morbidities. About 50% of MDS patients have one or more co-morbidities. They are independent predictors in MDS.¹

The aim of this study was to evaluate the influence of some prognostic factors in MDS (like age, gender, FAB subtypes, BM blast percentage, cytopenias, transfusion dependence, serum levels of ferritin, lactate dehydrogenase and albumin, comorbidities and specific karyotype abnormalities) on OS.

MATERIAL AND METHODS

Study setting and study subjects: We conducted a retrospective cohort study that included 154 adult patients with MDS who presented to the University Clinic of Hematology, Ss Cyril and Methodius University, Skopje, Macedonia, from January 2011 to June 2014. Observation time was 42 months. In addition to demographic data, we collected information on each patient's date of presentation and date of death/last follow-up. FAB classification, treatment and outcome were also obtained. This study was approved by the Ethical Board of the University and the procedures followed were in accordance with the Helsinki Declaration of 1975, revised in 2000.

Patients were evaluated for clinical and hematologic features at diagnosis and leukemic transformation. We evaluated some parameters that could influence OS: age, gender, BM blast percentage, red blood cell (RBC) transfusion dependence, serum levels of hemoglobin, ferritin, LDH and albumin as well as specific karyotype abnormalities. Most patients (pts) received supportive care: transfusion of RBC units and platelets, red cell and granulocyte growth factors - 23 pts (14.9%), corticosteroids, iron chelation therapy - 7 pts (4.5%), chemotherapy - 10 pts (6.5%), 1 patient (0.6%) was treated with azacytidine and 3 patients (1.9%) underwent allogeneic transplantation. Leukemic transformation was noticed in 7 patients (4.5%). Mortality was 35.1% (54 patients). Infectious and hemorrhagic complications as well as BM failure were considered causes of MDS-related deaths.

Statistical analysis: Descriptive statistics of the study population, including means (with corresponding standard deviations), medians (with corresponding ranges) and proportions, were computed. Differences among variables were evaluated by the Chi-square test. The determinations of correlations between different variables was based on the Pearson correlation coefficient and a certain correlation was considered statistically significant if $p < 0.05$. OS was calculated in months from day of presentation to the time of death

/ time of last visit. Observations were censored for patients at the last follow-up date. The probabilities of OS were estimated using Kaplan and Meier method. Cox proportional hazards regression models were used to assess the association between prognostic factors and OS. The statistical analyses were carried out using statistical package STATISTICA 8.0.

RESULTS

A total of 154 adult patients were included in this cohort study. OS was 13.1 months. (Figure 1) Median age at presentation was 65,8 years (SD 14,96) (range 17 to 89 years). The correlation between OS as a dependent variable and age as an independent variable was not statistically significant ($p = .80847$). When patients were divided in five groups: the first ≤ 50 years (26 patients) - OS 13,6 months (SD 9,36), the second 51-60 years (13 patients) - OS 13,7 months (SD 8,48), the third 61-70 years (35 patients) - OS 13,8 months (SD 11,32), the fourth 71-80 years (55 patients) - OS 13,5 months (SD 11,19) and the fifth >80 years (24 patients) - OS 9,9 months (SD 9,93), but the differences in OS among groups were not statistically significant ($p = .49751$). When patients were divided in two groups, OS in the first group ≤ 65 years (60 patients) was 13,4 months (SD 9,18) and in the second group >65 years (93 patients) - 12,8 months (SD 11,29), showing no significant difference ($p = .15760$). Surviving at 42 months in the first group was 77,5% and in the second 90,7%.

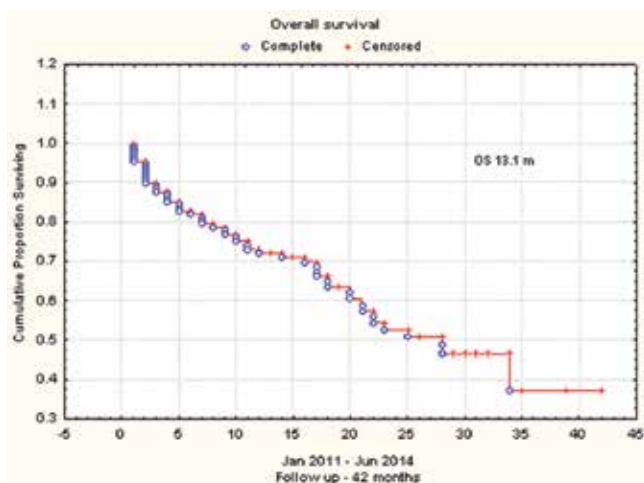


Figure 1. OS in the cohort followed for 42 months.

In this cohort 81 patients (52,6%) were male and 73 (47,4%) female. Male to female ratio was 1,11 to 1. Males had better OS than females - 13,0 (SD 10,62) versus 12,9 months (SD 10,37), being not significant ($p = .44569$). Surviving at 46

months was 82,4% for males and 83,1% for females. The correlation between OS and gender was not significant ($p = .974895$).

The correlation between OS and FAB subtypes was not significant ($p = .231835$). According to the FAB classification patients were classified as follows: 108 patients as having refractory anemia (RA) - 70%, 3 patients - RA with ringed sideroblasts (RARS) - 2%, 26 patients - RA with excess of blasts (RAEB) - 17%, 5 patients - RAEB in transformation (RAEB-T) - 6%, 9 patients - chronic myelomonocytic leukemia (CMML) - 3% and 3 patients - secondary MDS (MDSs) - 2%. (Figure 2)

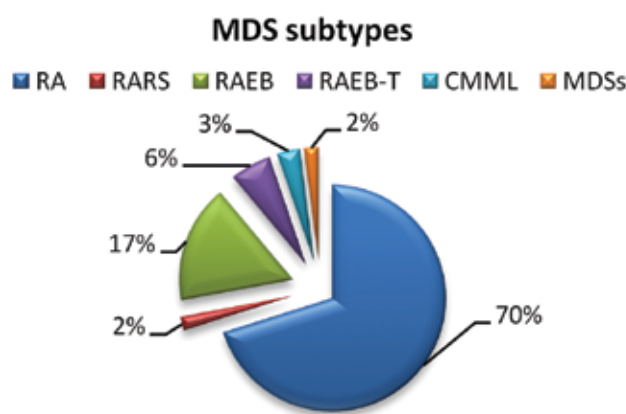


Figure 2. Distribution of FAB subtypes in percentage.

OS in patients with RA was 13,9 months (SD 10,75), with RARS - 7,0 months (SD 10,39), with RAEB - 9,3 months (SD 9,16), with RAEB-T - 7,8 months (SD 7,05), with CMML - 15,0 months (SD 8,23) and with MDSs - 18,0 months (SD 16,52), and the differences in OS were significant ($p = .01133$). (Figure 3)

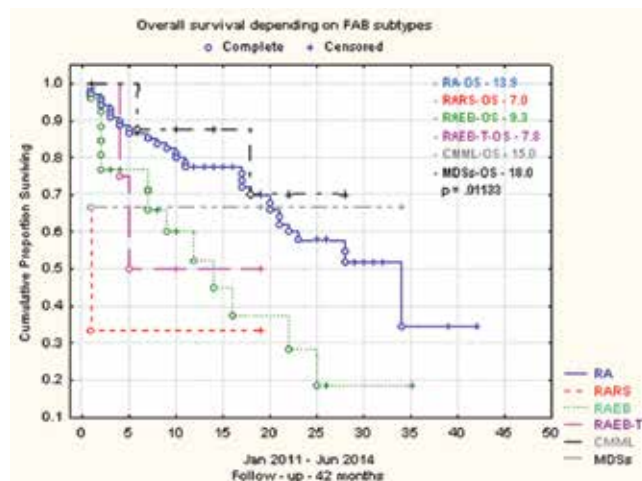


Figure 3. Differences in OS among FAB subtypes

The correlation between OS and BM blast percentage was statistically significant ($p = .028026$). Mean BM blast percentage was 6.3% (SD 6.72). OS in the group with <5% blasts (114 patients) was 14.4 months (SD 10.78), in the group with blasts 5-10% (15 patients) - 9.9 months (SD 9.87), with blasts 11-20% (18 patients) - 8.5 months (SD 7.85) and in the group with 21-30% blasts (7 patients) - 8.3 months (SD 7.61), the differences being significant ($p = .00757$). (Figure 4)

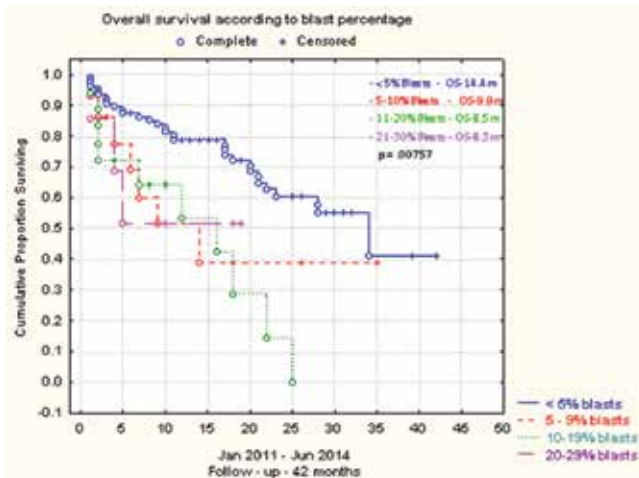


Figure 4. Differences in OS according to the blast percentage

The correlation between OS and hemoglobin was not statistically significant ($p = .179970$). Mean hemoglobin (Hb) level in our cohort was 8.61g/dl (SD 24.42) (range 4.1-15.0 g/dl). The patients were divided in three categories according to the severity of anemia: severe anemia (Hb <8.0 g/dl), moderate anemia (Hb 8.0-10.0 g/dl) and patients with Hb >10.0 g/dl. OS in the group with Hb >10.0 g/dl (63 patients) was 15.4 months (SD 10.76), in the group with Hb 8.0-10.0 g/dl (51 patients) - 11.5 months (SD 8.87) and in the group with Hb <10.0g/dl (36 patients) - 15.8 months (SD 11.99), the differences being not significant ($p = .24980$).

The correlation between OS and hemoglobin was statistically significant ($p = .386355$). Mean platelet count was $136.8 \times 10^9/l$ (SD 122.82) (range 3-629). Patients were divided in two groups: the first with platelet count < $100 \times 10^9/l$ (80 patients) - OS - 12.0 months (SD 9.57) and the second with platelet count > $100 \times 10^9/l$ (72 patients) - OS - 14.1 months (SD 11.46), the differences being not significant ($p = .20496$).

The correlation between OS and ANC was not statistically significant ($p = .972602$). Mean ANC was ANC 3042 cells/mm³ (SD 4.29) (range 200 - 34800 cells/mm³). Patients

were divided in three groups according to the ANC: the first with ANC < 500 cells/mm³ (12 patients) - OS - 12.2 months (SD 9.79), the second with ANC - 500-1000 cells/mm³ (20 patients) - OS - 13.2 months (SD 9.87) and the third with ANC >1000 cells/mm³ (120 patients) - OS - 13.0 months (SD 10.77), the differences being not significant ($p = .79375$).

Mean level of serum ferritin in our group was 758.6µg/L (SD 841.96) (range 10.0-3940.0). The group with ferritin <500 µg/l (19 patients) had OS 9.4 months (SD 10.48) and the group with ferritin >500 µg/l (12 patients) had OS 16.7 months (SD 10.65), without significant differences in OS ($p = .84758$).

The correlation between OS and transfusion dependence was not statistically significant ($p = .445856$). Mean transfused RBC units were 11.6 (SD 15.09) (range 1-87). OS in the group without RBC (56 patients) was 12.0 months (SD 10.69), in the group that received ≤ 18 RBC (78 patients) - 11.8 months (SD 10.24) and the group that received >18 RBC (20 patients) - 20.4 months (SD 7.75), being not statistically significant ($p = .38876$).

The correlation between OS and albumin was not statistically significant ($p = .559900$). Mean albumin level in our cohort was 39.3g/l (SD 6.24) (range 21-49). The differences in OS were statistically significant ($p = .00316$) among the three groups with different albumin levels: the first with albumins <35 g/l (11 patients) - OS - 8.8 months (SD 9.79), the second with albumins 35-40g/l (14 patients) - OS - 13.7 months (SD 9.87) and the third with albumins >40 g/L (26 patients) - OS - 13.6 months (SD 10.77). (Figure 5)

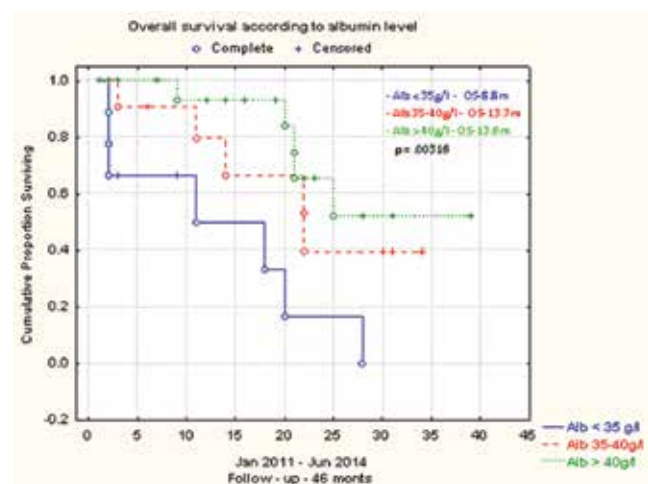


Figure 5. Differences in OS according to the albumin level

The correlation between OS and LDH was statistically significant ($p = .018895$). Mean serum level of LDH was 829.9 IU/l (SD 907.25) (range 217-5790). There was no significance in OS ($p = .18757$) between the two groups: the first with $LDH < 423$ IU/l (73 patients) - OS 15.7 months (SD 12.00) and the second with $LDH > 423$ IU/l (54 patients) - OS 10.7 months (SD 8.54).

Comorbidities as an independent variable had significant impact on OS ($p = .00386$). The difference in OS in the two groups was also significant ($p = .02278$) (Figure 4): the first with no comorbidities (126 patients) - OS 13.3 months (SD 10.28) and the second with comorbidities (27 patients) - OS 11.6 months (SD 11.59).

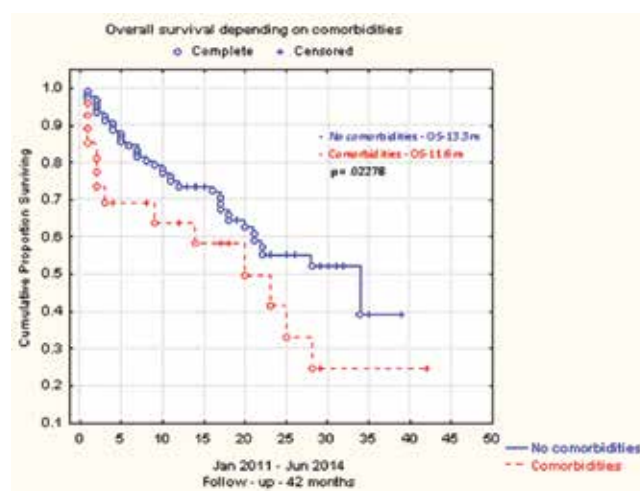


Figure 6. Differences in OS according to comorbidities

The correlation of joint effect of multiple variables (age, sex, FAB subtypes, BM blast percentage, hemoglobin, platelets, ANC, RBC transfusion, ferritin, albumin, LDH and comorbidities) on OS was statistically significant ($p = .01357$).

We were able to perform cytogenetic analysis only in 6 patients: 3 had normal karyotype, one had +8, one - inv16 and one - inv9 and inv13. Due to the small number of patients survival curves are not presented.

DISCUSSION

Our results considering age (65.8 years) correspond with those in the literature.⁸ Age did not affect OS neither as a whole nor stratified by subgroups, similar with some studies²³. Considering gender, men had slightly better OS than women, not corresponding with the data in the literature^{4,7}. FAB subtypes had a significant effect on OS. The worst results were observed in RAEB-T, than in

RAEB, RARS, RA and CMML subtype, similar with those in the literature.⁹ OS correlated inversely with BM blast percentage, showed also in other studies.^{24,25} Hemoglobin as a whole and stratified into subgroups did not show any impact on OS.²³ We could not demonstrate an impact of platelet count on OS. Also, prognostic significance of ANC was not demonstrated in our cohort.⁷ Serum ferritin level ≥ 500 $\mu\text{g/l}$ at diagnosis was a strong independent predictor of survival¹², although it was not the case in our cohort. Transfusion dependence is an independent prognostic factor for bad prognosis¹⁵, although in our group the impact on OS was not significant. LDH is a factor sited as having predictive value¹⁷, also proved in our cohort. Albumin is an independent prognostic factor in MDS patients⁸, but, in our group it had not significant impact on OS. Comorbidities were an independent prognostic factor for OS, which corresponds with data from the literature.¹ Cardiac diseases were the most frequent comorbidities. In our cohort only 6 patients were analyzed for cytogenetic abnormalities, three of them with good prognosis (normal cytogenetics) and three of them (+8, inv16 and inv9; inv13) with intermediate prognosis.

We can conclude that beside BM blast percentage, FAB subtypes, LDH and comorbidities are independent prognostic factors for OS in MDS. This should be proved in larger cohort studies and later proposed to be considered for future revisions of IPSS in order to refine the prediction of prognosis in MDS.

Limitations in our study include retrospective analysis, insufficient data on cytogenetic analysis and impossibility to stratify patients according to IPSS score, lack of data on some variables that probably reflected on the results, making them different than those cited in the literature.

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ПОВРЗАНОСТ НА ПРОГНОСТИЧКИТЕ ФАКТОРИ СО ПРЕЖИВУВАЊЕТО КАЈ МИЕЛОДИСПЛАСТИЧНИТЕ СИНДРОМИ: СТУДИЈА НА КОХОРТА

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АПСТРАКТ

Вовед: Миелодиспластичните синдроми (МДС) се хетерогена група на заболувања во однос на клиничката слика, лабораториските наоди и очекуваните преживувања. Многу студии се превземени со цел да се одредат факторите кои можат да ги прецизираат предвидувањата на прогнозата за МДС.

Цели: Целта на оваа студија беше да се евалуираат прогностичките фактори кои имаат влијание врз преживувањето кај МДС.

Методи: ова е ретроспективна анализа на кохорта од 154 адултни пациенти (81 маж, 73 жени) со МДС дијагностицирани на Универзитетската клиника за хематологија, Универзитет „Св.Кирил и Методиј“, Скопје, Македонија, во периодот од јануари 2011 до јуни 2014 година. Собрани се демографски податоци, како и податоци за ФАБ поттиповите, третманот на пациентите и исходот од терапијата.

Резултати: Возраста и полот немаа влијание на преживувањето ($p=.80847$ и $p=.974895$, соодветно). Различните ФАБ поттипови имаа влијание врз преживувањето ($p = .00757$). Процентот на бласти во коскена срцевина (КС) корелираше значајно со преживувањето ($p= .028026$). Хемоглобинот, бројот на тромбоцитите и апсолутниот број на неутрофили (АБН) не влијааа на преживувањето ($p= .179970$, $p= .386355$ и $p= .972602$, соодветно). Трансфузиите не влијааа на преживувањето ($p= .445856$), како ни албумините ($p=.559900$). Лактат дехидрогеназата (ЛДХ) и коморбидитетите влијааа на преживувањето ($p= .018895$ и $p = .02278$, соодветно). Леукемична трансформација беше нотирана кај 7 (4.5%) пациенти. Морталитетот беше 35.1%.

Заклучок: ФАБ поттиповите, процентот на бласти во КС, ЛДХ, и коморбидитетите се независен предиктор за преживувањето и би требало да се земат во предвид при следни ревизии на Интернационалниот прогностички скоринг систем со цел да се рафинираат предвидувањата за прогнозата на МДС

Key words: миелодиспластичен синдроми, прогностички фактори, преживување.