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Original study
Originalni naučni rad
UDK 616.1-089-036.8
https://doi.org/10.2298/MPNS2204083M

TEN YEARS AFTER THE INTRODUCTION OF THE EUROPEAN SYSTEM FOR CARDIAC OPERATIVE RISK EVALUATION 2: A SINGLE CENTER VALIDATION

DESET GODINA OD UVOĐENJA EVROPSKOG SISTEMA ZA PROCENU KADIOHIRURŠKOG OPERATIVNOG RIZIKA 2: VALIDACIJA U JEDNOM CENTRU

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Summary

Introduction. The aim of this study was to evaluate the predictive value of the European System for Cardiac Operative Risk Evaluation II in adult patients with acquired heart diseases. **Material and Methods**. The research included a consecutive series of 6,031 patients who underwent coronary, valvular and combined cardiac surgical interventions in the period from January 15, 2015 to December 31, 2020. Model calibration was assessed by comparing the ratio of actual to expected postoperative mortality and using the Hosmer-Lemeshow test. The discriminative power was examined using the area under the receiver operating characteristic curve. **Results**. A total of 2,883 patients underwent isolated coronary surgery, 1,841 underwent valvular procedures, while a combined procedure was performed in 1,307 patients. The operative risk was moderately underestimated in the entire group, as well as in the group of patients who underwent surgical revascularization of the coronary arteries. In patients who underwent valvular surgery, the actual mortality rate was slightly overestimated, while in patients with combined procedures it was moderately underestimated. The European System for Cardiac Operative Risk Evaluation II showed excellent discriminative power in the whole group of patients undergoing surgery (area under the curve = 0.825, p < 0.0005). The cut-off value was 2.60, sensitivity 0.757 and specificity 0.750. The discriminative power of the model was excellent in the group of coronary patients (area under the curve = 0.810) as well as in the group with isolated valvular surgery (area under the curve = 0.815). In patients with combined procedures, the discriminatory power was very good (area under the curve = 0.775). **Conclusion.** The results of our single centre study show that European System for Cardiac Operative Risk Evaluation II predicts hospital mortality with satisfactory results in the entire group, but underestimates it when it comes to combined cardiac surgical procedures. The discriminative power of the model is excellent.

Key words: Cardiac Surgical Procedures; Hospital Mortality; Mortality; Adult; Risk Factors; Risk Assessment; Thoracic Surgery

Sažetak

Uvod. Cilj rada je da se proceni prediktivna moć Evropskog sistema za procenu operativnog rizika u kardiohirurgiji kod odraslih bolesnika sa stečenim oboljenjima srca. **Materijal i metode.** Istraživanje je obuhvatilo konsekutivnu seriju od 6.031 bolesnika operisanih u periodu od 15. januara do 31. decembra 2020. godine. Uključeni su bolesnici kojima su rađene koronarne, valvularne i kombinovane kardiohirurške intervencije. Kalibracija modela procenjena je poređenjem odnosa stvarnog i očekivanog postoperativnog mortaliteta i pomoću Hosmer-Lemešovog testa. Diskriminativna moć ispitana je pomoću *receiver operating characteristic curve*. **Rezultati.** Kod 2.883 bolesnika rađena je koronarna kardiohirurška intervencija, kod 1.841 valvularna, dok je kod njih 1.307 urađena kombinovana procedura. Za čitavu grupu, kao i za grupu bolesnika kod kojih je rađena hirurška revaskularizacija koronarnih arterija, operativni rizik bio je umereno potcenjen. Kod bolesnika kojima je rađena valvularna procedura stvarni mortalitet bio je blago precenjen, dok je kod bolesnika sa kombinovanim procedurama bio umereno potcenjen. Model Evropskog sistema pokazao je odličnu diskriminativnu moć u grupi svih operisanih bolesnika (*area under the curve* = 0,825, p < 0,0005). Granična vrednost bila je 2,60, senzitivnost 0,757, a specifičnost 0,750. Diskriminativna moć bila je odlična u grupi koronarnih bolesnika (*area under the curve* = 0,810), kao i u grupi sa izolovanom valvularnom hirurgijom (*area under the curve* = 0,815). Kod bolesnika sa kombinovanim procedurama, diskriminativna moć bila je vrlo dobra (*area under the curve* = 0,775). **Zaključak.** Rezultati istraživanja u našem centru pokazuju da Evropski sistem za procenu operativnog rizika u kardiohirurgiji zadovoljavajuće predviđa operativni rizik za čitavu grupu operisanih bolesnika, ali ga potcenjuje kada su u pitanju kombinovane kardiohirurške procedure. Diskriminativna moć je odlična.

Ključne reči: kardiohirurške procedure; bolnički mortalitet; mortalitet; odrasli; faktori rizika; procena rizika; grudna hirurgija

Introduction

The European System for Cardiac Operative Risk Evaluation (EuroSCORE) was developed in the period between 1995 and 1999 from a database of a multinational study performed in 8 European countries including 19,030 adult patients [1]. In the beginning, the system was additive and was quickly adopted, first in Europe and later in other countries [2, 3]. The logistic system was developed in

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Abbreviations

EuroSCORE	– European System for Cardiac Operative Risk Evaluation
AUC	– area under the curve
ICD	– Institute of Cardiovascular Diseases
O/E	– observed/expected
H-L	– Hosmer-Lemeshow
STS	– Society of Thoracic Surgeons
ACEF	– age, creatinine, ejection fraction

2003 and proved to be better, especially in the group of high-risk patients [4, 5].

The EuroSCORE model has been routinely used at the Institute of Cardiovascular Diseases (ICD) of Vojvodina since the beginning of 2001. The analysis of the results, two years later, showed that the model was accurate, and that there was no significant difference between expected (3.7%) and observed mortality (3.47%).

However, only a few years later, the accuracy of both additive and logistic EuroSCORE has been questioned, since many studies showed that the results were better than expected, especially in the low- and medium-risk groups, and worse than expected in high-risk groups [6, 7]. Similar results were obtained in our consecutive series of 4,675 operated coronary patients [8]. In other words, although it still managed to distinguish between low and high-risk patients, the model overestimated the risk in mild- and moderate-risk patients.

In order to improve the model, the latest model for evaluation of the results of operative risk in cardiac surgery, the EuroSCORE 2 was created. The model was based on the collected data of more than 22,000 operated patients (16,828 - group for creating a model and 5,553 - groups for its validation). The ICD Dedinje from Belgrade and ICD of Vojvodina from Sremska Kamenica contributed to the EuroSCORE 2 project with more than 800 patients [9, 10].

New relevant risk factors have been defined, and some old risk factors have been eliminated in line with the latest advances in cardiac surgery. After internal validation, the model showed very good power of discrimination [11]. The model was presented at the 25th Annual Meeting of the European Association for Cardio-Thoracic Surgery, Lisbon, Portugal, in 2011, and introduced in routine use in 2012. The initial results of the EuroSCORE 2 showed better prediction than the previous model [12].

In our first study, including 1,247 patients undergoing surgery during a period of 14 months, starting from the beginning of 2012, we concluded that the EuroSCORE 2 showed a satisfactory predictive value of hospital mortality with solid discriminative power [13].

The aim of this study was to evaluate the predictive value of the EuroSCORE 2 in more than 6,000 operated patients, a group big enough for more precise analysis of results, not only for all patients, but also in coronary, valvular and combined cardiac procedures separately.

Material and Methods

All 6,031 consecutive patients who underwent coronary, valvular or combined (coronary and valvular) cardiac surgery, in the period from January 15, 2015 to December 31, 2020, were included in this study. The EuroSCORE 2 was calculated prospectively using the formulas available at the EuroSCORE website (www.euroscore.org).

Statistical analysis was performed using the statistical software package SPSS Version 19. The statistical significance of the difference between the mean EuroSCORE 2 and the mean mortality was determined using the Student's t-test. The Pearson chi-square test was used to assess the correlation between the numerical variables. The calibration of the EuroSCORE 2 was assessed by comparing the observed (O) and the expected (E) hospital mortality ratio and by the Hosmer-Lemeshow (H-L) test. The discriminative power of the EuroSCORE 2 was examined using area under the receiver operating characteristic curve (AUC), where cut-off, sensitivity and specificity were determined. Measures of descriptive statistics included frequencies and percentages. Differences were considered significant if $p < 0.05$.

Results

The total number of patients who underwent surgery in the period of 6 years was 6,031. There were 2,883 patients with isolated coronary surgery, 1,841 with valvular procedures and 1,307 patients with combined (coronary and valvular) interventions. The difference between the mean EuroSCORE 2 in all patients in the six-year period compared to the average observed mortality rate was statistically significant ($p < 0.0005$). This difference was also statistically significant ($p < 0.0005$) in combined surgeries, while in coronary surgery ($p = 0.895$) and valvular surgery ($p = 0.402$) it was not statistically significant.

The observed mortality rate in all patients was moderately underestimated. In coronary surgery the observed mortality rate was also moderately underestimated, while in valvular surgery it was slightly overestimated. In combined surgeries, the observed mortality rate was moderately underestimated. The calibration of the EuroSCORE 2 through types of cardiac surgeries is shown in **Table 1**.

Differences in the mean EuroSCORE 2 and types of surgery were statistically significant ($p < 0.0005$). The type of surgery and the observed mortality rate were related ($p < 0.0005$).

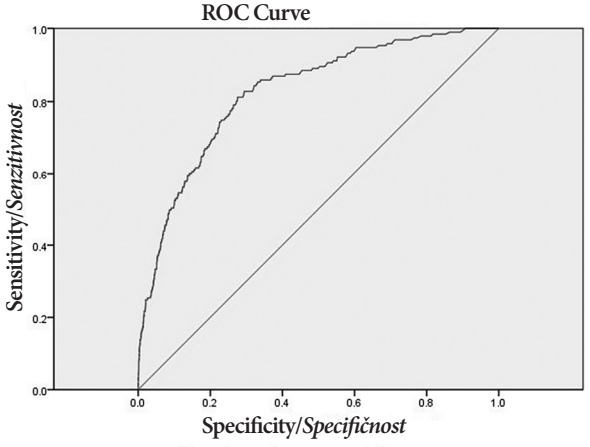
The calibration of the EuroSCORE 2 through the years, regarding, both H-L test and O/E mortality ratio, was good in 2016, 2017, 2018 and 2020, while in 2015 and 2019 the observed mortality ratio was higher than expected **(Table 2)**.

The EuroSCORE 2 showed an excellent discriminative power regarding the whole group of operated patients ($AUC = 0.825$, $p < 0.0005$). The

Table 1. Calibration of the EuroSCORE 2 in specific types of cardiac surgery
Tabela 1. *Kalibracija EvroSCORE 2 kroz tipove kardiohirurških procedura*

Type of surgery *Tip hirurške procedure*	Number of pts *Broj pacijenata*	EuroSCORE 2 (Expected mortality % *Očekivani mortalitet %*)	Observed mortality % *Stvarni mortalitet %*	O/E mortality ratio (95% confidence interval)/*Odnos očekivanog (E) i (O) stvarnog mortaliteta* (95% *interval poverenja*)	H-L test p value *Hosmer-Lemešov test, vrednost p*
Coronary *Koronarna*	2883	1.74	1.90	1.11 (1.08 – 1.17)	< 0.0005
Valvular *Valvularna*	1841	2.70	2.60	0.96 (0.89 – 1.05)	0.002
Combined *Kombinovana*	1307	5.05	6.50	1.29 (1.20 – 1.39)	0.009
Total/*Ukupno*	6031	2.75	3.13	1.14 (1.09 – 1.19)	< 0.0005

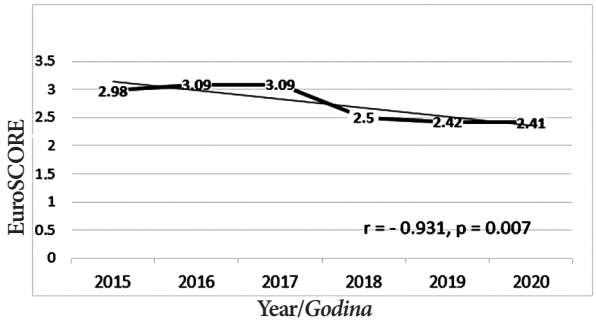
Legenda: EvroSCORE – Evropski sistem za procenu operativnog rizika u kardiohirurgiji



Graph 1. Discriminative power of the EuroSCORE 2
Grafikon 1. *Diskriminativna moć EvroSCORE 2 modela*

cut-off value was 2.60, sensitivity 0.757 and specificity 0.750 **(Graph 1)**.

The discriminative power of the EuroSCORE 2 **(Table 3)** was excellent in coronary surgery (AUC = 0.810) and valvular surgery (AUC = 0.815), but also very good in combined procedures (AUC = 0.775). The discriminative power of EuroSCORE in all three types of surgeries was very similar, while



Graph 2. The trend of the mean EuroSCORE 2 from 2015 to 2020
Grafikon 2. *Trend srednje vrednosti EvroSCORE 2 od 2015. do 2020.*

the difference in areas below the curves between valvular (maximum) and combined (minimum) surgery was not statistically significant (p = 0.409).

The discriminative power of the EuroSCORE 2 through the years, was excellent in the whole observed period **(Table 4)**, but only good in 2016 (AUC = 0.736).

The mean EuroSCORE 2 and observed years had a very strong negative correlation (r = - 0.928, p < 0.0005). The mean EuroSCORE 2 decreased from 2.98 in 2015 to 2.41 in 2020 (p < 0.0005). The

Table 2. The calibration abilities of the EuroSCORE 2 in the observed years
Tabela 2. *Moć kalibracije EvroSCORE 2 modela kroz godine*

Year *Godina*	Number of pts/*Broj pacijenata*	EuroSCORE 2 (Expected mortality % *Očekivani mortalitet %*)	Observed mortality % *Stvarni mortalitet*	O/E mortality ratio (95% confidence interval)/*Odnos očekivanog (E) i (O) stvarnog mortaliteta (95% interval poverenja)*	H-L test p value *Hosmer-Lemešov test, vrednost p*
2015	732	2.98	3.40	1.14 (1.04 – 1.15)	0.005
2016	1104	3.09	3.30	1.06 (0.97 – 1.15)	0.126
2017	1072	3.09	3.20	1.03 (0.93 – 1.14)	0.482
2018	1216	2.50	2.50	1.00 (0.91 – 1.14)	0.994
2019	1152	2.42	3.70	1.54 (1.40 – 1.72)	< 0.0005
2020	755	2.41	2.70	1.12 (0.97 – 1.27)	0.226
Total/*Ukupno*	6031	2.75	3.13	1.14 (1.09 – 1.19)	< 0.0005

Legenda: EvroSCORE – Evropski sistem za procenu operativnog rizika u kardiohirurgiji

Table 3. Discriminative power of the EuroSCORE 2 in specific types of cardiac surgery
Tabela 3. *Diskriminativna moć EvroSCORE 2 modela kroz tipove kardiohirurških procedura*

Type of surgery *Tip hirurške procedure*	AUC (95% confidence interval)/*Površina ispod krive (95% interval poverenja)*	Cut-off *Granična vrednost*	Sensitivity *Senzitivnost*	Specificity *Specifičnost*
Coronary/*Koronarna*	0.810 (0.752 - 0.869)	2.05	0.768	0.792
Valvular/*Valvularna*	0.815 (0.749 - 0.881)	2.45	0.750	0.755
Combined/*Kombinovana*	0.775 (0.726 - 0.825)	4.19	0.706	0.309

Legend: AUC - area under the receiver operating characteristic curve
Legenda: AUC – površina ispod krive, EvroSCORE – Evropski sistem za procenu operativnog rizika u kardiohirurgiji

Table 4. Discriminative power of the EuroSCORE 2 through the observed years
Tabela 4. *Diskriminativna moć EvroSCORE 2 modela kroz godine*

Year *Godina*	AUC (95% confidence interval)/*Površina ispod krive (95% interval poverenja)*	Cut-off *Granična vrednost*	Sensitivity *Senzitivnost*	Specificity *Specifičnos*t
2015	0.858 (0.792 -0.925)	3.77	0.840	0.813
2016	0.736 (0.658 – 0.813)	2.67	0.667	0.695
2017	0.823 (0.740 – 0.905)	3.00	0.765	0.769
2018	0.821 (0.749 – 0.892)	2.80	0.710	0.817
2019	0.863 (0.809 – 0.917)	2.75	0.791	0.821
2020	0.863 (782 – 0.944)	2.78	0.750	0,800
2015 - 2020	0.825 (0.795 – 0.855)	2,60	0.757	0.750

Legend: AUC - area under the receiver operating characteristic curve
Legenda: AUC – površina ispod krive, EvroSCORE – Evropski sistem za procenu operativnog rizika u kardiohirurgiji

trend of the mean EuroSCORE 2 from 2015 to 2020 is shown in **Graph 2.**

Discussion

According to the results of this study, the observed mortality rate in all patients was moderately underestimated, as well as in coronary and combined surgery subgroups. However, in valvular surgery the observed mortality rate was slightly overestimated. The calibration of the EuroSCORE 2 through years, regarding both H-L test and O/E mortality ratio, was good in 2016, 2017, 2018 and 2020, while in 2015 and 2019 the operative risk was underestimated. The EuroSCORE 2 showed excellent discriminative power regarding the whole group of operated patients in the period of six years, as well as in coronary surgery and valvular surgery, but very good in combined procedures. The discriminative power of the EuroSCORE 2 through the years was excellent in the whole observed period, but just good in 2016 year. The mean EuroSCORE 2 and observed years had a very strong negative correlation. The mean EuroSCORE 2 decreased from 2.98 in 2015 to 2.41 in 2020, but it was very good in combined procedures.

Similar results were published by Howell NJ et al., based on analysis of all three EuroSCORE models, in more than 12,000 operated patients from two European centers. Among those, there were 933 high-risk patients, whose logistic EuroSCORE was higher than 10. The conclusion was that the discriminative power of all three EuroSCORE models was good, but that in the group with increased risk, EuroSCORE 2 did not show better accuracy compared to the initial versions [14].

Paparella et al. presented an external validation of the EuroSCORE 2, based on the results of 6,293 operated coronary patients. According to their results, the discriminative power of EuroSCORE 2 was excellent (AUC = 0.830). Compared to calibration, in patients with lower and moderate risk, the model proved to be a good predictor of hospital mortality, while in those at increased risk, the operative risk was underestimated [15].

Similar results were published by Koszta et al. after the analysis of 2,287 operated patients in relation to the type of surgical intervention. In coronary surgeries, O/E ratio was 0.75 and the H-L test, p = 0.5789. In elective surgeries, O/E ratio was 1.1; H-L test, p = 0.139, and in emergency surgeries O/E ratio was 1.71; H-L test, p = 0.055. The conclusion was that the EuroSCORE 2 predicted better, compared to the initial models, but that it underestimated mortality in increased operative risk groups, related to emergency and combined surgery [16].

A preliminary research conducted at the ICD of Vojvodina in 2014, included 1,247 operated patients and showed good results in coronary and valvular surgery, but the results related to combined procedures, were not satisfactory [13].

A meta-analysis of Guida et al., that included 22 studies, including more than 145,000 cardiac surgical procedures, showed that the model had very good discriminative power (AUC = 0.792 and an O/E ratio: 1.019) for all procedures [17]. In isolated

coronary surgery, EuroSCORE 2 overestimated the risk (O/E ratio: 0.829). However, in the high-risk group, the model underestimated the mortality (O/E ratio: 1,253).

Nežic et al. from ICD Dedinje, Serbia, in a study of 1,864 patients, validated the EuroSCORE 2 [18]. The calibration was good for all groups, for coronary, valvular and combined surgeries. The discriminative power was acceptable only in combined surgeries (AUC = 0.72), but excellent in coronary surgery (AUC = 0.81), valvular surgery (AUC = 0.91), as well as in all patients (AUC = 0.85). In 2019, the authors from the same institution, reported performances of the EuroSCORE 2, including 10,048 operated patients [10]. The results were similar to those obtained in their previous study. Although H-L test did not perform well, O/E mortality ratio confirmed good calibration. The discriminative power for the whole group was excellent (AUC = 0.84), as well as in coronary surgery (AUC = 0.84) and valvular surgery (AUC = 0.86), while in combined surgeries it was very good (AUC = 0.78).

A multicenter study, conducted in 41 hospitals in Great Britain and Ireland, included 23,740 procedures, and Grant SW. et al. confirmed very good discriminative power (AUC = 0.808) and good calibration of the EuroSCORE 2. The results were better than predicted in coronary surgery, but the model failed the H-L test (p = 0.003), mainly due to overprediction in the highest and lowest-risk patients [19].

There are a large number of risk stratification models in cardiac surgery, which must be constantly revised and updated, because new risk factors must be considered. For any risk factor to be considered acceptable, it must, at a minimum, have an independent statistical relationship with the outcome and an advantage over the pre-existing predictors. An independent statistical correlation should be based on studies including large samples. The power of the model means that predictions of the outcome can be made as accurately as possible with as few parameters as possible. If there are a large number of variables in the model, multicollinearity may occur. The Society of Thoracic Surgeon (STS) model showed good accuracy in more than 138,000 subjects, but its disadvantage is that it considers a total of 33 risk factors [20, 21]. In contrast, the model proposed by Ranucci et al., created only for elective cardiac surgeries, has only 3 variables: age, serum creatinine level, and left ventricular ejection fraction (ACEF) [22].

The validation of a model is done based on its calibration (predictive power) and discriminative power. A good calibration means that the difference between the expected outcome and the observed outcome is small, ideally zero. The discriminative power of the model is the ability to distinguish between low and high-risk groups in relation to the outcome.

Numerous factors contributed to the fact that in the first decade of the 20th century there were significant changes in cardiac surgery. This refers to the continuous improvement of invasive cardiology procedures, preoperative preparation of patients, anesthesiological approach, surgical tactics and techniques, and postoperative treatment. The changes and advances in surgical treatment can serve as arguments to explain why the predictive power of the additive and logistic EuroSCORE has been decreased. This shows that overestimation of mortality rate was caused by improvements in peri-operative patient care. Apart from that, the expected mortality rate, given by the predictive model, is a standard that should at least be reached, but the aspiration is to be better. This effect, of increasing efficiency and improving quality due to the introduction of measurement results, is known as the Hawthorne effect [23, 24].

Barili et al. analyzed a consecutive series of 12,325 operated patients in Italy and compared all three EuroSCORE models. They concluded that the new model had good discriminative power, but was not more precise than the initial, additive, and logistic version [12].

Similar results were published by Howell NJ et al., based on the results of all three EuroSCORE models, in more than 12,000 operated patients from two European centers. Among those, there were 933 high-risk patients, whose logistic EuroSCORE was higher than 10. The conclusion was that the discriminative power of all three EuroSCORE models was good, but that in the group with increased risk EuroSCORE 2 did not show better accuracy compared to the initial versions [14].

Many authors have compared the two most well-known and widespread systems for evaluation of cardiac operative risk; the EuroSCORE 2 and the STS model. Kirmani et al. reported that both systems have similar discriminative power and good calibration in low-risk and moderate-risk patients [25]. Similar results were published by Sullivan PG. et al. in a meta analysis of differences in discriminative power of the EuroSCORE 2, STS and ACEF models. In conclusion, the EuroSCORE 2 and STS scores had similar discriminative power, better than ACEF score [26].

In our study, we analyzed not only the clinical performances of the EuroSCORE 2 for a total period of 6 years, but also the calibration and discrimination properties of the EuroSCORE 2 through the years. The discriminative power of the EuroSCORE 2 through the years was excellent in the whole observed period. It was found that the mean EuroSCORE 2 and observed years had a very strong negative correlation. The mean value of the EuroSCORE 2 decreased from 2.98 in 2015 year, to 2.41 in 2020. The mean value of the model has a declining trend. We could not find published studies evaluating the trend of the mean EuroSCORE 2 through the years. It would be interesting to assess this finding, 10 years after its introduction.

The limitation of our study is a relatively small sample size for more precise analysis, especially in subgroups of cardiac surgery patients. Furthermore, it is a single-center experience and the results may not represent national and international practice and

outcomes. More multicenter studies, including a greater number of patients, are necessary for more precise evaluation of the results.

Conclusion

In conclusion, the results of our single center study show that the European System for Cardiac Operative Risk Evaluation 2 predicts hospital mortality with satisfactory results concerning the whole group, but underestimates mortality in patients undergoing combined cardiac procedures. The discriminative power of the model is excellent.

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Rad je primljen 16. X 2022.
Recenziran 23. X 2022.
Prihvaćen za štampu 31. X 2022.
BIBLID.0025-8105:(2022):LXXV:3-4:83-88.