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Abstract

Introduction: Ulcerative colitis belongs to the group of IBD, inflammatory bowel disease, a chronic inflammatory disease with relapses, occurs at any age, more common in young or middle-aged people. The incidence in the US is around 10 - 12 cases per year per 100,000, with a peak incidence at the age of 15 - 25, and the prevalence is 1/1000. Inflammation almost always affects the rectum, is continuous and can affect the entire colon, spreads in the mucosa and to a lesser extent in the submucosa. The main histological features are crypt abscesses, disturbed crypt architecture and mucin depletion. In 55% of cases desease has a form of proctitis, in 30% has the form of left-sided colitis, and in 15% as extensive colitis. It is a chronic inflammatory disease, which imposes the need for more precise measurement of the degree of its activity. Clinicians use laboratory parameters such as sedimentation (ESR), C reactive protein (CRP), leucocytes (WBC) or platelet (Plt), associated with frequent invasive methods (endoscopic assessments)for assessing the activity of ulcerative colitis (UC). Powell-Tuck index or Mayo score similar to the Disease Activity Index (DAI) described by Sutherland., *et al.* are used, Powell-Tuck index from 1978 includes some laboratory like ESR, RBC (red blood cells), Alb. (albumins), or clinical parameters such as the presence of tachycardia, elevated temperature, dehydration.

Aim of the Study: To show the value of clinical scores in assessing UC activity. To compare scores and individual laboratory parameters in the assessment of UC activity.

Materials and Methods: Retrospective study conducted on patients treated at the Department of Gastroenterology and Surgery of the General Hospital Leskovac and Gastroenterology Clinic of Clinical Center Nis, from January 2015 to December 2019. Diagnosis based on history, clinical parameters, laboratory, endoscopy with pathohistology, radiological exploration. Patients older than 18 years, and up to 83 years are included, average age 54.69 ± 17.32 years. Total of 72 patients, 41 (57%) men and 31 (43%) women, and divided, according to clinical parameters into three groups related to disease activity: mild (10 patients,13.9%), moderate (47 patients, 65.3%) and severe (15 patients, 20.8%) disease. We used and compared the values of complete and partial, as well as numerical two-component score to monitor disease activity, together with endoscopic and laboratory parameters. We used Pearson correlation test and Student t statistical tests.

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Results: We demonstrated a statistically significant correlation between the Mayo score and the simplified partial (r = 0.93, p = 0.01) and numerical Mayo score (r = 0.73, p = 0.01) in the assessment of UC activity, as well as between the partial and numerical Mayo score (r = 0.81, p = 0.01). We have thus proved that partial Mayo scores and 6-point numerical scores composed only of components such as stool count and bleeding can be as effective as full Mayo scores in assessing UC activity and determining the clinical response in patients. Based on significant differences between clinical stages of UC, we detected different levels of ESR (p < 0.05), Fe (serum iron) (p < 0.05), and Alb. (p < 0.05).

Conclusion: The significance of these parameters is that a simple assessment of disease activity is achieved, without frequent use of invasive methods, with a very correlated value with the complete Mayo score and numeric two component score. Of the laboratory parameters, level of ESR, Fe, and Alb., could play a significant role in assessing UC activity.

Keywords: Ulcerative Colitis; Mayo Score; Correlation

Introduction

Ulcerative colitis/UC/, which belongs to the group of inflammatory bowel diseases/IBD/, is a chronic inflammatory disease with relapses, which occurs at any age, but more often in younger or middle-aged people. The annual incidence of UC is 24.3 per 100,000 personyears in Europe, 6.3 per 100,000 person-years in Asia and the Middle East, and 19.2 per 100,000 person-years in North America. The highest prevalence of UC is in Europe UC, 505 per 100,000 persons; North America UC, 249 per 100,000 persons; The incidence in the USA is somewhere around 10 - 12 cases per 100,000 per year, with the peak incidence at the age of 15 - 25 years, and the prevalence is 1/10,000 [1].

The inflammation almost always affects the rectum, it is continuous and can affect the entire colon, and it spreads in the mucosa and to a lesser extent in the submucosa. The main histological characteristics are crypt abscesses, disturbed crypt architecture and mucin depletion [2]. In 55% of cases it appears in the form of proctitis, in 30% it has the form of left-sided colitis (up to F. Lienalis) and in 15% as extensive colitis, with involvement of the transfersum and more proximally [3,4]. It is a chronic inflammatory disease prone to relapses, which necessitates a more precise measurement of the degree of its activity. Many clinicians use simple laboratory parameters such as sedimentation rate (ESR), C reactive protein (CRP), Le count (WBC) or platelet count (Plat). In clinical studies, these parameters are often accompanied by frequent invasive methods/endoscopic evaluations/, with the necessary adequate preparation. For the purpose of evaluating the activity of ulcerative colitis (UC), the Mayo score, Powell-Tuck index, or Mayo score similar to the Disease Activity Index (DAI) described by Sutherland., *et al.* The Powell-Tuck index from 1978 also includes some laboratory (Se, RBC/HTC, and Alb) and clinical parameters such as the presence of tachycardia, elevated temperature, dehydration, etc [5].

In recent years, the literature has emphasized the importance of the so-called "mucosal healing" parameter, as the ultimate goal of successful UC therapy, as a short-term and long-term prognosis parameter, /definition of endoscopic remission: Ulcerative Colitis Endoscopic Index of Severity (UCEIS) 0, and reduction of Mayo endoscopic score ≥ 1 or reduction of UCEIS ≥ 2 to define endoscopic response to therapy in UC, and the term of histological healing is also an option, the parameters of which are still incompletely defined [6]. There is still no valid definition of histological healing, but it has been suggested that this term could mean the absence of fragility, bleeding, erosion and ulceration in all considered segments of the intestine [7]. The most frequently applied pathohistological scores are Geboes score and Nancy score [8].

In this regard, endoscopy could be taken as the "gold standard" in the assessment of UC activity, especially in the follow-up protocols of larger studies. In the study by Schoepfler., *et al.* it was proven that for ileocolic and colonic localization of the disease, elevated fecal mark-

ers, calprotectin and lactoferrin, as well as PMN elastase in the study by Langhorstai., et al. from 2016, can be a reliable surrogate marker for endoscopically and histologically inactive IBD [9,10].

Aomatsu., *et al.* show that the fecal level of CHI3L1/Chitinase 3-like-1 (CHI3L1) shows a strong affinity for chitin, a polymer of N-acetyl glucosamine, which can be useful in assessing the severity and activity of mucosal inflammation in pediatric IBD patients, in the adult population Buisson and colleagues also prove a good correlation of the level of both biochemistry markers with the endoscopic degree of IBD activity [10-12].

Thorsvik., *et al.* prove that Fecal NGAL /Neutrophil gelatinase-associated lipocalin (NGAL)/ also known as lipocalin 2 is a promising biomarker for IBD. Existing biomarkers are mostly in granulocytes, NGAL is mostly with epithelial localization and can provide additional diagnostic quality [13].

Treatment od severe cases of UC, often demands inclusion of TPN (total parenteral nutrition), but clinicians should be aware of PN exposure-related adverse events are the following: intestinal-inflammation, compromised intestinal permeability, increased bacterial translocation, aberrant microbiome barrier function, cholangitis, cholelithiasis, short bowel syndrome, asynchronous hepatobiliary circulation, adiposity, dysbiosis, insulin resistance, so nutrition should be directed towards enteral nutrition [14].

With the obesity pandemic, non-alcoholic fatty liver disease (NAFLD) has become the most prevalent liver disease. NAFLD can progress to non-alcoholic steatohepatitis (NASH), a potential cause of liver failure. Increased risk for NASH, because of contributing factors, including genetic variance, hormones, adipokines, diet and body-fat distribution, and chronic administration of steroids (during the course of severe UC) [15].

Objective of the Study

- The aim was to show the utility value of clinical scores in the assessment of UC activity.
- The aim was to compare endoscopic and simplified scores in the assessment of UC activity.
- The aim was to compare scores and individual biohumoral parameters in the assessment of UC activity.

Materials and Methods

Retrospective study conducted on patients treated at the Gastroenterology Department of Leskovac General Hospital from January 2015 to December 2019. Diagnosis based on history, clinical parameters, laboratory, endoscopy with pathohistology, radiological exploration. Patients older than 18 years were included. And up to 83 years, average age 54.69 ± 17.32 years. A total of 72 patients, 41 men and 31 women, and divided, according to clinical parameters, into three groups according to disease activity: mild, moderate and severe form of the disease.

All patients underwent clinical and laboratory examination with reference to parameters of inflammation, ESR, WBC, CRP, then HG, HTC, RBC, Alb, Plat, Fe, MCV, with mandatory endoscopic and pathohistological confirmation of the disease. All patients were classified by grade according to the clinical and endoscopic parameters contained in the Mayo score.

According to the clinical and endoscopic parameters contained in the Mayo score, all patients were classified according to the severity of the disease into three groups. BYOCHEMICAL ANALYZER AU-680-ZA of the central biochemical laboratory of the Clinical Center was used for biochemistry analysis and Olympus video colonoscope, Olympus EXERA CV-160 video processor, with CLV-160 xenon light source was used for endoscopic examinations of patients.

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UC activity in patients was also assessed according to the parameters included in the partial Mayo score, which does not include endoscopy parameters, as well as according to the simplest 6-point Likert scale which grades only the number of stools and the degree of bleeding. The values obtained by these scores were compared using the Pearson correlation statistical test. The mean values of certain laboratory parameters between these groups were compared and statistically analyzed.

| Desease activity tests compared | Correlation grade/coefficient- r | P Value | |
|---------------------------------|----------------------------------|---------|--|
| Completed Mayo/Partial Mayo | 0.93 | 0.01 | |
| Partial Mayo/Numeric score | 0.81 | 0.01 | |
| Completed Mayo/Numeric score | 0.73 | 0.01 | |

Table: Level of correlation between complete and partial Mayo/numerical score of disease activity

 Coefficient of correlation and p value were calculated using Pearson Correlation test.

Statistical tests of arithmetic mean, standard deviation, χ^2 test with Yates correction, correlation test and Student's t test were used.

Results

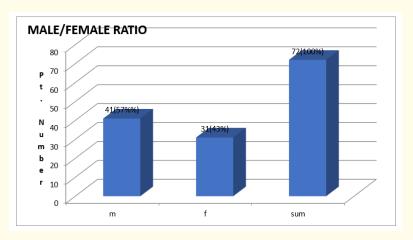


Diagram 1: Shows the ratio of gender representation of patients in the examined population.

Our study included a total of 72 patients with UC, of which 41 were male and 31 were female. According to our results, gender does not affect the severity of the clinical picture, using the Chi square test. $\chi^2 = 0.98 < \chi^2$ (1 and 0.05) = 3.84 and p > 0.05. Odds ratio = 1.17 (0.67 < OR < 4.34) RR=1.07 (0.67 < RR < 1.71) Taylor series 95%. Confident Limits for RR.

The average age of patients with a mild form of UC is 55.1 years. And in the groups with moderate and severe form it was 54.69 years. T = 0.94 < t (SS and 0.05) = $1.99 \Rightarrow (p > 0.05)$, there is no statistically significant difference in the average age. There is also no statistically significant difference between the group with mild and severe form of UC, t = 0.67 < t (SS and 0.05) = 2.06 (p > 0.05).

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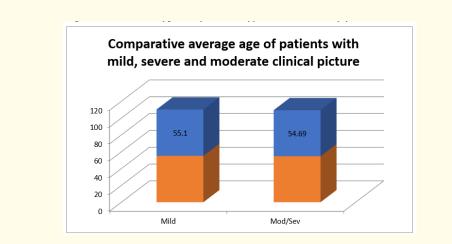


Diagram 2: Shows comparative average age of patients with mild, severe and moderate clinical picture.

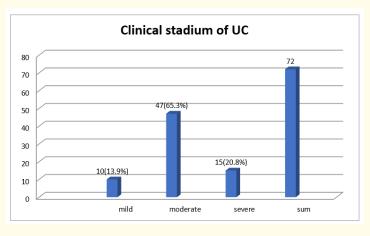


Diagram 3: Shows the proportion of patients according to clinical stage.

In the observed population, the group with a moderate severity of the clinical picture (47 patients) is the most numerous, then the group with a severe clinical picture (15 patients) and finally the group with a mild form (10 patients). The average values of the complete Mayo score differ significantly between mild and severe forms of UC, t = 4.81 > t (23, i 0.05) = 2.07, the values of the numerical Mayo score also differ significantly between the mild and severe stage, t = 6.09 > t (23 and 0.05) = 2.07.

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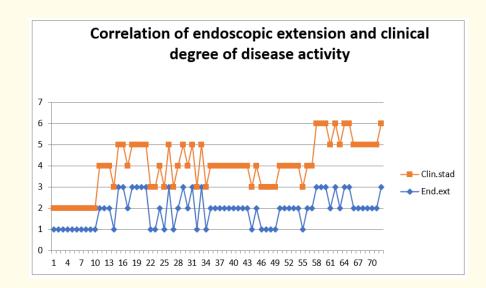


Diagram 4: Shows the correlation of endoscopic extension and clinical degree of disease activity. r = 0.56 the correlation between the degree of endoscopic extension and the clinical stage of disease activity/Mayo score/which was established in the observed population belongs to the correlations of the medium degree of connection p < 0.01.

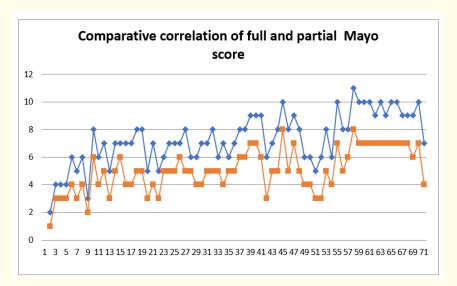


Diagram 5: Shows comparative correlation of partial and full Mayo scorer = 0.92 correlation ratio between the Mayo value and the partial Mayo score of UC activity in the observed population, p < 0.01, there is a high degree of positive correlation.

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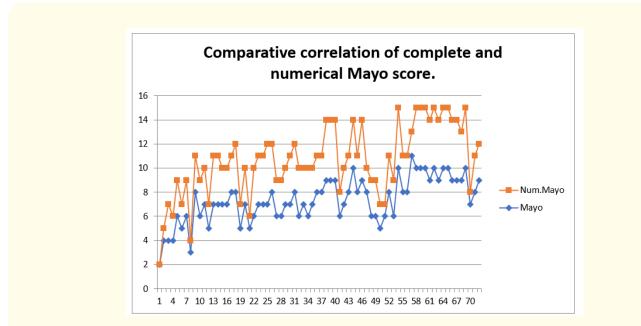


Diagram 6: Shows comparative correlation of complete and numerical Mayo score. r = 0.73 Correlation ratio between the Mayo value and the numerical Mayo score of UC activity in the observed population, p < 0.01, there is a high degree of positive correlation.

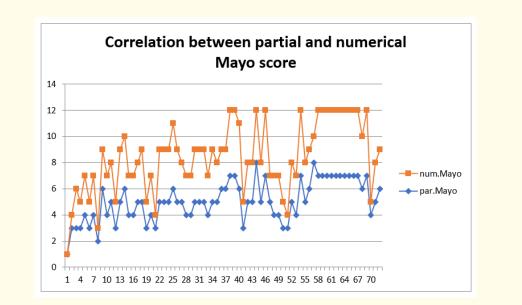


Diagram 7: Shows comparative correlation of partial and numerical Mayo score. r = 0.81 correlation of the value of the partial Mayo score and the average score of 6 points of UC activity in the observed population, shows a high degree of positive association p < 0.01.

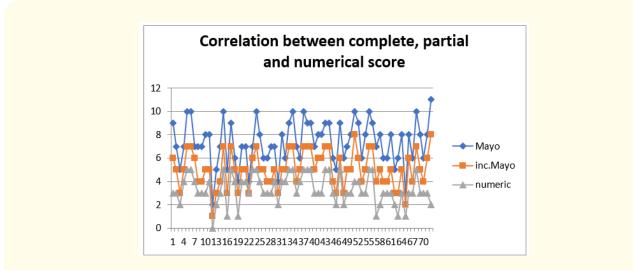


Diagram 8: Chows comparative correlation of full, partial and numerical Mayo score.

The diagram shows a comparative correlation of the values of the complete, partial and numerical Mayo score in the examined population, a high degree of correlation has been proven between all the mentioned variants of the Mayo score, i.e. Between complete and partial r = 0.93 (p = 0.01), as well as between complete and numerical two-component Mayo score version r = 0.73 (p = 0.01), including a high correlation between partial Mayo and two-component numerical Mayo score.

Discussion

UC is an idiopathic disease that occurs as a result of the interaction of genetic factors and exposure to environmental factors. Crohn's disease and ulcerative colitis do not show extreme differences between the sexes in both incidence and prevalence, only sporadic evidence not based on large, well-designed studies indicated that female gender is related to the clinical picture in CD/Crohn's Disease/,

| Mild UC | N | Mean | STDEV |
|---------|----|-------|--------|
| CRP | 10 | 20.55 | 24.54 |
| ESR | 10 | 17.90 | 11.76 |
| RBC | 10 | 4.33 | 0.61 |
| Нg | 10 | 124.7 | 29.58 |
| НТС | 10 | 37.23 | 8.00 |
| WBC | 10 | 8.15 | 3.51 |
| Plat | 10 | 323.1 | 130.48 |
| Fe | 10 | 14.28 | 8.54 |
| MCV | 10 | 75.75 | 7.81 |
| Alb | 10 | 40.3 | 5.25 |

Table 1: Shows descriptive statistics of biochemistry findings of mild form of UC.

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| Moder.UC | N | Mean | STDEV | |
|----------|----------|--------|--------|--|
| CRP | 47 | 47.69 | 53.99 | |
| ESR | 47 | 40.60 | 25.85 | |
| RBC | 47 | 3.99 | 0.75 | |
| Hg | 47 | 121.68 | 21.18 | |
| НТС | 47 | 44.83 | 57.7 | |
| WBC | 47 | 8.62 | 3.15 | |
| Plat | 47 | 290.48 | 131.08 | |
| Fe | 47 | 8.71 | 6.06 | |
| MCV | 47 77.48 | | 4.91 | |
| Alb | 47 | 35.74 | 6.36 | |

Table 2: Shows descriptive statistics of biochemistry findings of the moderate UC group.

| Severe UC | N | Mean | STDEV | |
|-----------|----|--------|--------|--|
| CRP | 15 | 90.70 | 79.95 | |
| ESR | 15 | 73.53 | 34.9 | |
| RBC | 15 | 3.90 | 0.72 | |
| Нg | 15 | 106.26 | 23.27 | |
| НТС | 15 | 33.14 | 4.72 | |
| WBC | 15 | 12.55 | 4.70 | |
| Plat | 15 | 404.13 | 147.30 | |
| Fe | 15 | 4.80 | 3.84 | |
| MCV | 15 | 76.33 | 6.67 | |
| Alb | 15 | 30.8 | 6.18 | |

Table 3: Shows descriptive statistics of biochemistry findings of the group of severe form of UC.

| | CRP | ESR | RBC | Hg | НТС | WBC | Plat | Fe | MCV | Alb |
|----------|-------|-------|-----|----|-----|------|------|------|-----|------|
| Mild/Sev | Sign. | Sign. | NS | NS | NS | Sign | NS | Sign | NS | Sign |

Table 4: Shows significance of differences between laboratory parameters depending on the severity of the clinical picture.

On table 4 biochemistry analyzes were presented, the mean values of which were compared between groups, and the Student's T test found significant differences between groups with mild and severe forms of UC when it comes to CRP values, t = 2.73 > t (23 and 0.05) = 2.07 p < 0.05; ESR values also differ significantly between these groups of patients by Student's T test t = 2.82 > t (23 and 0.05) = 2.07 p < 0.05; It was found that WBC values differ significantly between these groups by Student's T test, t = 2.58 > t (23 and p 0.05) = 2.07 p < 0.05;

When it comes to serum Fe values, a statistically significant difference was found by Student's T test between these groups of patients t = 3.88 > (23 and 0.01) = 2.82 p < 0.01;

Albumin values are significantly different between these groups of patients by Student's T test t = 4.07 > (23 and 0.01) = 2.82 p < 0.01;A statistically significant difference between the mean values of the Mayo score in patients with mild and severe forms of UC was also verified, Student's T test, t = 6.09 > (23 and 0.01) = 2.82 p < 0.01.

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while UC is more often present in males, according to Goodman., *et al.* [16], which is in accordance with the results of our study, where the χ^2 test proved that there is no significant difference in the distribution of the clinical degree of severity of UC of the observed group according to gender, as well as that there is no significant difference in the average age of patients between patients with the most severe and the mildest clinical picture (Diagram 1 and 2). Extra intestinal manifestations, especially rheumatological conditions and Fe-deficient anemia, in many studies were more often manifested in females, but those studies were geographically limited and with a small number of subjects, and it is believed that these tendencies could be related to the influence of hormonal status in women. In these studies, an increased incidence of CRC was established in male patients with long-standing IBD compared to females, and in connection with the potential influence of hormonal factors on the course of the disease and pregnancy, it is recommended that fertile women with IBD should plan possible conception in periods of disease remission [17,18].

The highest percentage of patients in our study, about 65%, belonged to the group of moderate disease activity according to the applied Mayo score, and about 13% had a mild and 20% with a severe clinical picture (Diagram 3), there is also a positive correlation with the endoscopic extent of the disease medium grade, as we proved in our study (Diagram 4), which is also mentioned by Balint., *et al.* in their study on 104 patients, published in 2018, in which they offered a modified pan Mayo score of a maximum of 45 points in which, in addition to the usual endoscopic Mayo score added and calculated value of the score of endoscopic expansion, as a parameter of correlation of endoscopic and clinical activity of the disease and endoscopic degree of extensity. The Pan Mayo score showed a moderate degree of correlation with the endoscopic Mayo score was not significant. It is significant that in this study the authors also found a high correlation between the Pan Mayo score and the histological score according to Riley, although other studies mention a lower degree of correlation (medium degree) of clinical and histological scores, although different histological scores are questionable as Nancy and Geboes [19].

In our series of patients, we proved a high degree of correlation (r = 0.92) between the values of the full and partial Mayo score, which includes clinical parameters without endoscopy, which is shown by the coincidence of the curves in diagram 5. This data is supported by the statements in the review paper of Peyrin-Biroulet and associates from 2016 [20]. Lewis., et al. in their study from 2008, on 45 subjects, also showed a useful value with a high degree of correlation of the partial and complete Mayo score for monitoring the condition of patients during treatment with Rosiglitazine [21]. Diagram 6 shows the correlation curve between the full Mayo score and the numerical two-component so-called. Likert scale, in our respondents it was established that there is a high degree of correlation/r =0.73/ between these scores, and on the diagram 7 and 8 show the curve of a high degree of correlation between the partial Mayo score and the two-component Likert score (r = 0.81), as well as the comparative correlation curves of all three variants of the Mayo score used in our study, which is similar to the results of the study by Lewis., et al. from 2008 with 105 patients where the established degree of correlation between these scores was r = 0.88. According to Higgins, et al. who in their series of 66 patients compared the correlation of invasive and non-invasive scoring systems (St. Marks index and UCDAI with SSCAI and SEO index), a high degree of correlation was also found (0.86 and 0.70), so that the authors conclude that the contribution of the endoscopic component in the standard scores for assessing UC activity is small, and that for a satisfactory clinical assessment it is sufficient to monitor parameters such as stool frequency and the occurrence and degree of bleeding, analogous to the Likert score used in our study, which is of importance for simplification and better patient compliance in clinical studies [22]. In the study by Pagnini., et al. on 75 patients from 2015, a high degree of correlation of clinical and indices that also imply the use of endoscopic criteria was also proven, with a slightly lower degree of correlation (medium degree, for the Mayo score r = 0.35) with histological scores. However, the authors conclude that the histological analysis of inflammatory changes in UC provides additional contribution in the prognostic sense and predictive significance regarding the risk of possible future exacerbation, i.e. that minimal histological changes (especially related to the degree of presence of basal plasma cells in the mucosa) probably mean a longer period of remission. On table 1 descriptive statistical values of the group of patients with a mild form of UC are shown, and table 2 and 3 show descriptive statistical values of the group with a moderate and severe form of UC. It is observed that there is a visible deviation in the values of certain biochemistry parameters, especially between the groups with a mild and severe form of the disease.

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In our series of patients, the Student's t test found a statistically significant difference in the mean values of CRP between the groups with severe and mild clinical picture, which is in accordance with the found good correlation of CRP and clinical scores for UC in the aforementioned study by Pagnini., et al [23]. We also found a statistically significant difference in the mean value of Le between the mentioned groups of patients, which is analogous to the results of a prospective study by Ricanek., et al. we do not find a significant alteration of the number of Plat. in connection with the activity of UC [24]. The erythrocyte sedimentation rate (ESR) is the next biochemistry parameter that in our study also differs significantly between the group with a mild and severe clinical picture and can be monitored as an indicator of the degree of IBD activity, which correlates with other clinical and biochemistry parameters, as stated in review work by Rodriques and associates from 2020 [25]. A significant difference in serum albumin level was found between the groups with mild and severe clinical form of patients in our study, analogous to the results of the study by Mak and associates from 2020, which was conducted on 113 patients, and which also proved the importance of biochemistry markers such as are the level of Albumin, CRP, platelets, hemoglobin, ESR, but also fecal markers (Calprotectin, FIT) in monitoring the activity of IBD [26]. Finally, the registered level of serum iron in patients in our study differs significantly between the groups with mild and severe form of UC. In the review work of Nielsen and associates from 2018, a significant number of patients with IBD have a reduced level of serum iron and transferrin saturation, according to these authors, a "cut off" value of 16% saturation is indicated for substitution therapy with Fe preparations, although a value of 20% is often mentioned in the literature due to the presence of the inflammation factor. Serum ferritin is also an important parameter according to these authors, because its value in patients with IBD is partially influenced by different degrees of inflammation, which through increased expression due to cytokine stimulation can raise ferritin values independently of the level of available iron. Therefore, in these conditions, a ferritin level below 30 µg/L is certainly considered an iron deficiency, but also a ferritin value over 100 µg/L, due to the presence of chronic inflammation, can be associated with functional anemia and iron deficiency. In patients with more severe forms of IBD and more pronounced inflammation, as well as in patients who show intolerance or poor response to oral therapy and in conditions where a rapid therapeutic response and improvement of quality of life is required, parenteral preparations of Fe for i.v. application are indicated, with adequate dosage according to the calculated total iron deficit in the body, as well as monitoring for possible adverse reactions (anaphylaxis) [27]. The retrospective character of our study and the relatively small number of patients are its limiting factors of objectivity, which imposes the need for further research on a more representative sample as well as a possible meta-analysis of data obtained from a larger number of similar studies published so far.

Conclusion

We proved a statistically significant correlation between the Mayo score and simplified partial and numerical Mayo scores in the assessment of UC activity, as well as between the partial and numerical Mayo scores. Likert scores composed only of components such as stool count and bleeding may be as effective as the full Mayo score in assessing UC activity and determining clinical response in patients. The importance of these parameters is that a quick and simple assessment of disease activity is achieved, without the frequent use of invasive methods (endoscopic evaluations), with a highly correlating value with the complete Mayo score, which is more convenient for patients and can increase compliance. The correlation between the degree of endoscopic extension and the clinical stage of disease activity (by the Mayo score) has been proven. Further research on a larger number of patients in the assessment of these indicators of UC activity is necessary for a better assessment of their validity. In our study, no significant difference in the frequency or severity of the clinical picture of UC between the sexes was proven. In our study, no significant correlation between the average ages by clinical stages was proven. Of the laboratory parameters, based on significant differences between the clinical stages of UC, the level of CRP, ESR, Le, Fe and Alb could play a significant role in the assessment of UC activity.

Disclosure

Nothing to disclose.

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