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Comparison of Scores for Predictability of Corticosteroid Failure in Patients With Acute Severe Ulcerative Colitis

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SUMMARY

Introduction: Methylprednisolone and hydrocortisone are the first-line drugs in the treatment of acute severe ulcerative colitis (ASUC). The Oxford index and the Lindgren score are two of several prognostic systems for the early assessment of corticosteroid (CS) failure.

Aim: The aim of the study was to determine the clinical course and treatment outcome of patients with ASUC and the difference between the Oxford criteria and the Lindgren score in identifying patients with CS-refractory ASUC.

Material and Methods: A retrospective clinical trial included 30 patients with ASUC. They were divided into a group with complete response to intravenous CS therapy and one without. Demographic and clinical parameters associated with CS failure were analyzed statistically. In order to test the hypotheses, a chi-square test was applied.

Results: After the third day of therapy, 70% of patients did not have a complete response to CS therapy based on the Oxford index value. These patients had a 91% higher risk of receiving rescue therapy (infliximab), while this risk is 2.67 times higher in patients with a Lindgren score >8 (it was recorded in 53.3% of patients). Statistically significantly lower values of the Lindgren score were found in the group with a complete response to CS therapy. A third of the patients from the examined group received rescue therapy, no patient was surgically treated and there were no cases of fatal outcome. In relation to rescue therapy, the Lindgren score >8 showed a higher positive predictive value (62.5% vs 47.6%) and higher specificity (70% vs 45%) than the Oxford index, while the negative predictive value and sensitivity of both scores amounted to 100%.

Conclusion: Pharmacotherapy with intravenous CS was effective in most acute severe ulcerative colitis patients, but in a certain number of patients it was necessary to include rescue therapy. The Lindgren scoring system is specific and has a higher predictive value in identifying CS-refractory patients compared to the Oxford index values.

Keywords: Ulcerative Colitis, Corticosteroids, Oxford, Lindgren

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INTRODUCTION

Ulcerative colitis (UC) is a chronic inflammatory bowel disease characterized by periods of remission and relapse [1]. UC typically affects the colon in a continuous manner, most often starting from the rectum, with lesions limited to the mucosa and submucosa [2]. UC has two peaks of incidence: the first occurs in the second or third decade of life, and the second between the ages of fifty and eighty. The symptoms of UC include frequent, bloody stools, nocturnal bowel movements, and lower abdominal pain [3]. Approximately 15-25% of patients will develop acute severe ulcerative colitis (ASUC), which requires urgent hospitalization, early diagnosis, and initiation of therapy to reduce the risk of complications and enable a favorable outcome. The mortality rate is about 1%, and the colectomy rate can be as high as 30% [5-8].

First-line medications for ASUC treatment are intravenous corticosteroids (CS): methylprednisolone at a dose of 60 mg daily and hydrocortisone 300-400 mg daily in multiple doses. These medications are not withheld even if there is a concurrent *Clostridium difficile* infection [9]. To prevent thromboembolic complications, low molecular weight heparin is administered [10]. The success of CS therapy is tipically evaluated on the third day of treatment [4].

There are several prognostic scoring systems for early assessment of CS refractoriness. The Oxford index includes the presence of ≥8 bloody stools per day and/or CRP >45 mg/l on the third day of treatment; if one of the criteria is positive, the risk of CS refractoriness is 85% [11]. The Lindgren score (number of stools in 24 hours + 0.14 x CRP) exceeding eight on the third day of therapy is associated with a high risk of colectomy (up to 69%) [12]. Indicators of a poor response include: >8 stools daily or 3-8 stools with CRP >45 mg/l [4]. In such cases, second-line therapy (rescue therapy) with infliximab (IFX) is considered. If remission is achieved within the next 3-5 days, IFX is continued according to a specific protocol [9]. An alternative second-line therapy is intravenous cyclosporine at a dose of 2 mg/kg daily [13]. However, this treatment is accompanied by numerous contraindications, poorer tolerability, and the need for monitoring drug concentration. The simpler administration of IFX along with the introduction of biosimilars (which have reduced the cost of IFX) still makes IFX the first choice [14]. Indications for surgical treatment (colectomy) include CS-refractory ASUC, toxic megacolon, massive uncontrolled bleeding, shock, and perforation [15].

AIM

The aim of the study was to determine the clinical course and treatment outcomes of patients with ASUC. Additionally, the goal was to compare between the Oxford criteria and the Lindgren score in identifying patients with CS-refractory ASUC.

MATERIAL AND METHODS

The study was conducted as a retrospective, cross-sectional, academic (no commercial) study of patients with ASUC who were divided into a group that responded well to CS and a group that was refractory to CS. The study was approved by the Ethics Committee of the University Clinical Center of Vojvodina (approval number 00-318, December 15, 2023). It included 30 consecutive adult patients with ASUC who were hospitalized at the Clinic for Gastroenterology and Hepatology of the University Clinical Center of Vojvodina from January 2022 to September 2023. The diagnosis of ASUC was based on the Truelove and Witts (T-W) criteria. All patients underwent flexible rectosigmoidoscopy (FRS) with mucosal biopsies on the day of admission, without prior bowel preparation, and the Mayo endoscopic score (MES) was calculated. Examinations were performed using an Olympus CF-HQ1100DL colonoscope connected to the Olympus EVIS X1 CV-1500 system.

Treatment was conducted in accordance with the current guidelines from leading organizations in the field of inflammatory bowel diseases [3,4]. All patients received intravenous methylprednisolone (Lemod®-Solu, Hemofarm AD Vršac) at a dose of 60 mg daily and thromboprophylaxis with subcutaneous low molecular weight heparin (Fraxiparine®, Aspen Notre Dame de Bondeville) upon admission, along with parenteral fluid replacement based on clinical status, and anemia, hypoalbuminemia, and electrolyte imbalance were corrected according to laboratory results.

Laboratory tests were performed at the Center for Laboratory Medicine of the

Table 1. Characteristics of the total sample in the study

Number of Participants, n	30
Age, M ± SD, years	41.07 ± 17.01
Gender, n (%)	
male	16 (53.3)
female	14 (46.7)
Smoking Status, n (%)	
smokers	6 (20%)
non-smokers	24 (80%)
Truelove-Witts Criteria, n (%)	
T-W 1+1	12 (40.0%)
T-W 1+2	13 (43.3%)
T-W 1+3	5 (16.7%)
Mayo Endoscopic Score, n (%)	
MES 2	6 (20%)
MES 3	24 (80%)
Oxford Criteria on the Third Day, n (%)	
responded to therapy	9 (30%)
did not respond to therapy	21 (70%)
Oxford Criteria on the Seventh Day, n (%)	
responded to therapy	8 (38.1%)
did not respond to therapy	13 (61.9%)
Lindgren Score, n (%)	
<8	14 (46.7%)
>8	16 (53.3%)
Infliximab, n (%)	
yes	10 (33.3%)
no	20 (667%)

University Clinical Center of Vojvodina. Hemoglobin concentration was determined using a colorimetric method on a Sysmex XN-1000 SA-01 machine. The albumin level was measured using a spectrophotometric method on an Abbott Alinity C automated biochemical analyzer, and CRP was assessed using an immunoturbidimetric method.

On the third day of hospitalization, the response to therapy was evaluated:

- Patients with a complete response, according to the Oxford criteria (<4 stools per day, cessation of bleeding, and CRP <45 mg/ml), were switched to oral prednisone and discharged from the hospital;
- Patients with >8 stools per day and/or CRP >45 mg/l received intravenous IFX (Remsima, Nuvisan France Sarl) at a dose of 5 mg/kg body weight;
- Patients with a partial response continued to receive intravenous methylprednisolone until the seventh day, and if there was still no complete response, they were given intravenous IFX at a dose of 5 mg/kg body weight.

Daily assessments were conducted to monitor the patients' conditions and determine the need for surgical intervention in cases of complications or failure of medical therapy.

Data entry and analysis for this study were performed using the IBM SPSS 23.0 software package. To describe the sample, descriptive statistics were employed, including absolute numbers and percentages, measures of central tendency (mean, median), measures of variability (standard deviation), and extreme values (minimum and maximum). The normality of the distribution of continuous variables was assessed using the Kolmogorov-Smirnov test. To address the set goals and hypotheses, the chi-square test was applied as a non-parametric method of comparative statistics for nominal level data. Differences in means of continuous variables between dif-

Patients group		Response to therapy on the third day (number of patients)	
		Yes	No
Gender	Men	4	12
	Women	5	9
Smoking status	Smokers	3	3
	Non-smokers	6	18
Mayo Endoscopic Score	MES 2	3	3
	MES 3	6	18
Truelove-Witts Criteria	T-W 1+1	2	10
	T-W 1+2	6	7
	T-W 1+3	1	4
Lindgren Score	>8	1	15
	<8	8	6

Table 2. Response to therapy on the third day

ferent groups were tested using the t-test and the Mann-Whitney test where the data did not meet the criteria for parametric statistics. The results were presented both textually and graphically [16].

RESULTS

The total sample consisted of 30 patients with ASUC. Male patients accounted for 53.3% of the sample. The participants' ages ranged from 19 to 73 years, with a mean age of 41 years. One-fifth of the participants were smokers.

All patients met the T-W criteria. In addition to having >6 bloody stools per 24 hours, 40% of patients met one additional criterion (T-W 1+1), 43% met two additional criteria (T-W 1+2), and one-sixth of patients met three additional criteria (T-W 1+3). The majority of patients (24/30) had a Mayo Endoscopic Score (MES) of 3, a smaller number (6/30) had a MES of 2, while MES 1 and 0 were not recorded.

According to the Oxford criteria, on the third day of therapy, 70% of patients did not achieve a complete response to CS therapy. Among those, 61.9% also did not show a favorable effect of CS therapy by the seventh day. A Lindgren score >8 was noted in more than half of the patients (53.3%). Rescue therapy was administered to one-third of the patients. Three patients achieved complete response to CS therapy after the seventh day. No patients underwent surgical treatment, and there were no cases of fatal outcomes. A description of the sample is presented in Table 1.

To investigate the differences in demographic characteristics, T-W criteria, MES, and Lindgren scores between patients who achieved a complete response to therapy on the third day and those who did not, a series of chi-square tests were performed. The results showed that patients who had a complete response to therapy had a statistically significantly higher occurrence of a Lindgren score <8 compared to those who did not (88.9% vs 28.6%, χ^2=9.21, df 1, p=0.002). No significant differences were found between these two groups regarding: gender (χ^2=0.408, df 1, p=0.694), smoking status (χ^2=1.43, df 1, p=0.329), number of T-W criteria present (χ^2=2.87, df 2, p=0.238), individual T-W cri-

Characteristics	Complete Response	No Complete Response	p
Age (years)	38.33 ± 15.86	42.24 ± 17.72	0.559
Stools/24h at admission	9.89 ± 2.32	10.33 ± 3.84	0.700
Pulse at admission (/min)	98.33 ± 11.18	90.05 ± 15.33	0.113
Hemoglobin at admission (g/l)	123.11 ± 15.12	113.00 ± 28.60	0.218
CRP at admission (mg/l)	73.87 ± 33.16	92.33 ± 80.44	0.381
Albumin at admission (mg/l)	33.00 ± 6.32	32.41 ± 5.05	0.808
CRP on the third day (mg/l)	25.60 ± 10.71	33.65 ± 29.10	0.279
Lindgren Score	6.25 ± 1.35	11.04 ± 4.33	<0.001
CRP/Albumin at admission	2.38 ± 1.26	2.94 ± 2.71	0.448

Table 3. Differences in examined parameters between the two groups of patients

Table 4. Rescue therapy in two analyzed scores

Score		IFX therapy (number of patients)	
		Received	Not received
Oxford Index	Complete response	0	9
	Cortico-refractory	10	11
Lindgren Score	<8	0	14
	>8	10	6

teria (temperature, pulse, CRP, hemoglobin), or MES (χ^2=1.43, df 1, p=0.232). The response to therapy on the third day based on different parameters is shown in Table 2.

Table 3 presents the average age, average values of the T-W criteria, laboratory findings, and Lindgren scores in the group of patients who achieved a complete response to therapy on the third day compared to those who did not, along with the results of the t-test for independent samples conducted to assess the statistical significance of the differences in the obtained mean values between the two groups of patients. A difference was found only in the case of the Lindgren score, in that patients with a complete response on the third day of therapy had a statistically significantly lower Lindgren score (t=-4.59, df 26.7, p<0.001).

Infection with a toxin-producing strain of Clostridium difficile was recorded in only one patient from the total sample. Cytomegalovirus (CMV) status determination during the histological processing of colon biopsies was performed in half of the patients. In the group of CMV-negative patients, 30% (3/10) were CS-refractory and received rescue therapy, while in the group of CMV-positive patients, this number was 60% (3/5). The difference was not statistically significant (χ^2=0.313, df=1, p=0.329).

No patient with a complete response on the third day of therapy according to the Oxford criteria received IFX, whereas 47.6% of patients who did not achieve a complete response received IFX (Table 4). To assess whether there is a statistically significant association between the Oxford index and the administration of IFX, a chi-square test was conducted. The results revealed a statistically significant association between these two categorical variables (χ^2=4.46, df=1, p=0.013). Patients who did not achieve a complete response on the third day of therapy had a 91% higher risk of receiving rescue therapy (RR 1.91; 95% CI, 1.27-2.87).

No patient with a Lindgren score <8 received rescue therapy, while 62.5% of patients with a Lindgren score >8 received rescue therapy (Table 4). To examine the association between a Lindgren score >8 and the administration of rescue therapy, a chi-square test was conducted. The results indicate a statistically significant association between these two categorical variables (χ^2=10.5, df=1, p<0.001). Patients with a Lindgren score >8 had a 2.67 fold higher risk of receiving rescue therapy (RR 2.67; 95% CI, 1.42-5.02).

Table 5 presents the sensitivity, specificity, positive predictive value, and negative predictive value of the prognostic scores in relation to the administration of rescue therapy. The ROC analysis of the Lindgren score for predicting the failure of CS therapy is illustrated in Figure 1, with an AUC of 0.873 (p = 0.019, R^2 = 0.381). An optimal cut-off of 7.78 achieved sensitivity of 79.2%, specificity of 88.9%, PPV 94.12% and NPV 61.54%.

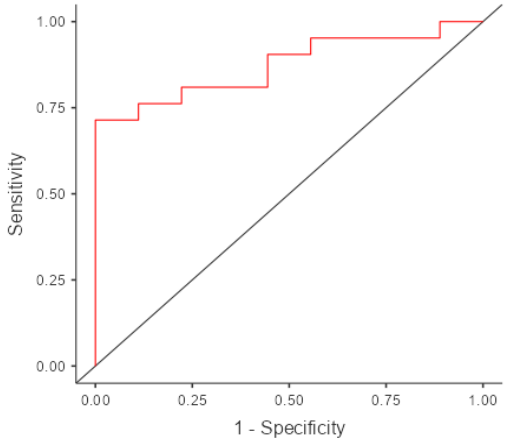

Figure 1. ROC curve analysis of the Lindgren score for predicting CS therapy failure

Table 5. Prognostic Scores and Rescue Therapy

	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Oxford Index	100	45	47.6	100
Lindgren >8	100	70	62.5	100

DISCUSSIONS

UC is a chronic inflammatory bowel disease that presents as ASUC in 15-25% of cases [1,4]. The aim of our study was to determine the clinical course of patients with ASUC, given the lack of literature regarding ASUC outcomes in our region, and to assess the difference between the Oxford criteria and Lindgren score in identifying patients with CS-refractory ASUC.

Our study included 30 consecutive patients hospitalized for ASUC. According to the Oxford criteria, 30% of patients in our study had a complete response by the third day of intravenous CS therapy. In the study by Bernardo et al., which included 112 episodes of ASUC, a complete response was achieved in 58% of cases by the third day of intravenous CS therapy [17].

In our study, patients had a nearly equal gender distribution, and the average age was 41 years. There was no statistically significant difference in age or gender distribution between CS-refractory patients and those with a complete response to corticosteroids, which aligns with findings from a larger Chinese study (n=129) [18]

The T-W criteria, published in 1955, have significant importance in diagnosing ASUC [6]. Although not designed to predict outcomes, these criteria have been linked to refractoriness and the risk of colectomy. Our study, on a limited number of patients, found no differences in the number of present T-W criteria between patients with a complete response and those with an incomplete response to CS. In the study by Dinesen et al., the number of present T-W criteria significantly influenced ASUC outcomes, with a threefold higher risk of colectomy if ≥2 additional T-W criteria were present compared to the presence of 1 additional T-W criterion [19].

Our results did not show a statistically significant difference in the MES between patients with a good response to intravenous CS and those who were CS-refractory. This contrasts with findings by Xie et al., where the risk of refractoriness in patients with MES 3 was significantly higher than in those with MES 2 (62.1% vs 11.5%, p<0.001) [20].

We found no statistically significant differences in CRP levels on admission and on the third day, albumin levels on admission, or CRP/albumin ratio on admission between patients with a complete response to CS and those who did not. This is contrary to the study by Gibson et al., where these laboratory parameters were significant predictors of CS refractoriness [21].

In our study, patients who had a complete response by the third day of intravenous CS therapy had a statistically significantly lower Lindgren score, which was expected [22]. Since no patient underwent surgery and there were no fatalities, the ultimate outcome for patients who did not respond favorably to intravenous CS during hospitalization was rescue therapy. Patients who did not achieve a complete response by the third day had a 91% higher risk of receiving rescue therapy, while the risk was 2.67 times higher if the Lindgren score was >8. Regarding rescue therapy, the Lindgren score >8 demonstrated a higher positive predictive value (PPV) (62.5% vs 47.6%) and greater specificity (70% vs 45%) than the Oxford index, while both scores had a negative predictive value (NPV) and sensitivity of 100%. The Lindgren score was significantly more predictive of the need for rescue therapy compared to the Oxford criteria, as also noted in the study by Bernardo and colleagues [17].

The main limitation of our study is the limited sample size and therefore insufficient statistical power. Future research should include a larger patient cohort in order to facilitate definitive conclusions.

CONCLUSION

Most patients with ASUC respond positively to intravenous CS, while a smaller number require rescue therapy. The Lindgren scoring system demonstrates greater specificity and positive predictive value compared to the Oxford index in identifying CS-refractory patients.

CONFLICTS OF INTEREST

All authors declare no conflict of interest.

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Poređenje skorova za predviđanje kortikorefrakternosti kod pacijenata sa akutnim teškim ulceroznim kolitisom

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KRATAK SADRŽAJ

Uvod: Metilprednizolon i hidrokortizon su lekovi prvog izbora u lečenju akutnog teškog ulceroznog kolitisa (ATUK). Oksfordski indeks i Lindgrenov skor su dva od nekoliko prognostičkih sistema za ranu procenu neuspeha kortikosteroida (KS).
Cilj: Cilj rada bio je da se utvrdi klinički tok i ishod lečenja pacijenata sa ATUK i razlika između Oksfordskih kriterijuma i Lindgrenovog skora u identifikaciji pacijenata sa ATUK refrakternim na KS.
Materijal i metode: Retrospektivno akademsko kliničko ispitivanje obuhvatilo je 30 pacijenata sa ATUK. Podeljeni su u grupu sa potpunim i bez potpunog odgovora na intravenski KS. Statistički su analizirani demografski i klinički parametri neuspeha kortikosteroida. U cilju provere hipoteza primenjen je hi-kvadrat test.
Rezultati: Nakon trećeg dana terapije, 70% pacijenata nije imalo potpuni odgovor na KS terapiju na osnovu vrednosti Oksfordskog indeksa. Ovi pacijenti imaju 91% veći rizik od primanja terapije spasa (infliksimab), dok je ovaj rizik 2,67 puta veći kod pacijenata sa Lindgren skor >8 (zabeleženo je kod 53,3% pacijenata). Statistički značajno niže vrednosti Lindgrenovog skora su nađene u grupi sa potpunim odgovorom na terapiju KS. Trećina pacijenata iz ispitivane grupe primila je terapiju spasa, nijedan pacijent nije hirurški lečen i nije bilo slučajeva smrtnog ishoda. U odnosu na terapiju spasa, Lindgrenov skor >8 pokazao je veću pozitivnu prediktivnu vrednost (62,5% prema 47,6%) i veću specifičnost (70% prema 45%) od Oksfordskog indeksa, dok su negativna prediktivna vrednost i osetljivost oba skora iznosile do 100%.
Zaključak: Farmakoterapija intravenskim KS je bila efikasna kod većine pacijenata sa ATUK, ali je kod određenog broja pacijenata bilo neophodno uključiti terapiju spasa. Lindgren sistem bodovanja je specifičan i ima veću prediktivnu vrednost u identifikaciji kortikorefrakternih pacijenata u poređenju sa vrednostima Oksfordskog indeksa.

Ključne reči: ulcerozni kolitis, kortikosteroidi, Oksford, Lindgren

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