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Validation of EncephalApp Stroop Test for Diagnosing Minimal Hepatic Encephalopathy in Romanian patients with liver cirrhosis

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ABSTRACT

Background & Aims: Minimal hepatic encephalopathy (MHE) represents the mildest form of hepatic encephalopathy. MHE has been associated with impairment of quality of life and job performance, and is a major cause of premature retiring in cirrhotic patients. However, MHE is usually overlooked by most physicians, due to its asymptomatic nature. We aim to present our experience with the EncephalApp Stroop Test for diagnosing MHE in cirrhotic patients. We also want to establish if Stroop test performance correlates with age, educational level, liver disease severity (as assessed by the MELD and Child-Pugh scores), duration of disease, previous episodes of overt hepatic encephalopathy, and other relevant clinical or laboratory parameters.
Methods: A cross-sectional observational single-center study, in which 100 adult patients diagnosed with liver cirrhosis were evaluated for the presence of MHE by using the EncephalApp Stroop Test. In parallel, 45 healthy adult controls without liver cirrhosis were recruited and tested under the same conditions as the patients.
Results: There were no age-related differences between the two groups (p=0.6). Stroop test performance of the controls (143.1 ± 20.8 seconds) was significantly better than that of the patients (171.9 ± 33.3 seconds) (p<0.0001). Stroop test results correlated with the MELD (R=0.28, p=0.005) and Child-Pugh scores (R=0.2, p=0.04). There was a positive correlation between Stroop test results and age in patients (R=0.45, p<0.0001) and controls (R=0.75, p<0.0001). Stroop test performance was not influenced by the duration of liver disease (p=0.4) or prior episodes of overt hepatic encephalopathy (p=0.25). Gender and level of education did not have an impact on Stroop test results. Alcoholic liver disease, diabetes mellitus, hyperglycemia, anemia and hyponatremia were associated with poorer performances.
Conclusions: EncephalApp Stroop Test proved to be a quick and simple method for diagnosing minimal hepatic encephalopathy in the hospital setting. Test performance was influenced primarily by age, but also by liver disease severity, anemia, hyponatremia and hyperglycemia.

Key words: minimal hepatic encephalopathy – MELD – subclinical hepatic encephalopathy – EncephalApp Stroop test.

Abbreviations: CT: computed tomography; HBV: hepatitis B virus; HCV: hepatitis C virus; HDV: hepatitis D virus; INR: international normalized ratio; MELD: model for end-stage liver disease; MHE: minimal hepatic encephalopathy; MMSE: mini-mental state examination; PHSE: Psychometric Hepatic Encephalopathy Score; RBANS: Repeatable Battery for the Assessment of Neuropsychological Status; SHE: subclinical hepatic encephalopathy.

INTRODUCTION

Subclinical hepatic encephalopathy (SHE) or minimal hepatic encephalopathy (MHE) represents the mildest form of hepatic encephalopathy [1]. Minimal hepatic encephalopathy is characterized by subtle cognitive deficits that are not apparent on a routine clinical examination, but are only identifiable through psychometric testing [2]. The presence of MHE has been associated with impairment of quality of life and job performance, and is a major cause of premature retiring in cirrhotic patients [3-5]. Minimal hepatic encephalopathy has also been associated with poor driving performance [6] and is an independent risk factor for poor survival [7]. However, it is usually overlooked by most physicians, due to its asymptomatic nature.

Over the years, numerous psychometric and neurophysiologic tests have been developed in order to accurately diagnose MHE. Of these, only the Psychometric Hepatic Encephalopathy Score (PHES) and Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) were nominated by a panel of experts to serve as potential "gold standard" for the assessment of MHE [8]. These tests are cheap and do not require sophisticated equipment in order to be administered, but they have some disadvantages as well, the most important being their dependence on a patient's age and education. They are also time consuming (15 to 20 minutes for PHES and 30 to 35 minutes for RBANS) and require a psychologist for administration [9].

EncephalApp Stroop Test is a recently developed software application for smartphones and tablets, with the purpose of diagnosing MHE in a simple and quick manner. It is based on the Stroop effect, described in 1935 by John Ridley Stroop [10].

We aim to present our experience with the EncephalApp Stroop Test for the diagnosis of MHE in cirrhotic patients. We also want to establish if poor Stroop test performance correlates with the severity of liver disease (as assessed by the MELD and Child-Pugh scores), duration of disease, previous episodes of overt HE, presence of portal vein thrombosis, ammonia levels, and other relevant clinical or laboratory parameters. Moreover, we would also like to establish if test performance is influenced by other factors, such as age, gender or patient's educational level.

METHODS

We performed a cross-sectional observational single-center study, in which 100 adult patients diagnosed with liver cirrhosis were evaluated for the presence of MHE by using the EncephalApp Stroop Test. Only patients who agreed to participate and gave an informed written consent were enrolled. Unlike other diagnostic procedures, this test is non-invasive and does not pose any risk to the patient's well-being or health status. Only patients who respected the inclusion and exclusion criteria of the study were selected (Table I).

Testing occurred on a tablet (Apple iPad Mini 4). A translated Romanian version of the EncephalApp Stroop Test was used. Each patient was tested during daytime in a quiet and naturally lighted room, with the patient seated at a table. All patients received prior training on the tablet and had to pass a trial test in order to confirm that they understood the objectives. We also placed emphasis on ruling out all possible causes of discomfort which could interfere with the patient's concentration (such as thirst, hunger, tiredness). The current cut-off value of > 190 seconds was used to define the presence of MHE.

All patients underwent laboratory workup, which included: complete blood count, serum albumin, total serum proteins, fibrinogen, INR, aspartate transaminase, alanine transaminase, total bilirubin, conjugated bilirubin, alkaline phosphatase, gamma-glutamyl transferase, lactate dehydrogenase, creatinine, urea, glycemia, total serum cholesterol, triglycerides, serum sodium, serum calcium, serum iron, serum magnesium, vitamin B12, folate, vitamin D3, serum ceruloplasmin and venous ammonia.

Other parameters (such as the presence of portal vein thrombosis, ascites and/or presence and severity of esophageal varices) were evaluated by abdominal ultrasound, abdominal CT scan and upper digestive endoscopy. Severity of liver function was measured using the MELD and Child-Pugh scores.

We also collected data regarding the patient's educational level (i.e. the last level of education completed, as well as the number of schooling years), current settlement (urban versus rural areas), duration of cirrhosis and prior episodes of overt hepatic encephalopathy.

In parallel, 45 healthy adult controls without liver cirrhosis were recruited and tested under the same conditions as the patients. All controls respected the same exclusion criteria and signed an informed consent regarding the participation in this study.

All medical information (imaging and laboratory results) was accessed using the hospital's informatic system Hipocrate. Patient database was created on Microsoft Excel 2021.

Statistical analysis was performed on MedCalc Statistical Software version 22.021.

This study was performed at the Gastroenterology and Hepatology Department of Fundeni Clinical Institute in Bucharest (Romania).

RESULTS

Demographic Results

Mean age of the patients was 50±9 years-old (range: 28-62 years-old). 70% were males. Most of the participants (73%) originated from urban areas, while 50% had a Bachelor's degree.

Table I. Inclusion and exclusion criteria for the assessment of minimal hepatic encephalopathy by using EncephalApp Stroop Test

Inclusion criteria	Exclusion criteria
▪ Age ≥ 18 year-old ▪ Established diagnosis of liver cirrhosis (regardless of disease duration or etiology)	▪ Overt hepatic encephalopathy at the time of assessment ▪ Wilson disease with neurologic involvement ▪ Uncorrected refractive errors ▪ Color blindness ▪ Lack of reading skills ▪ MMSE < 25 points ▪ Age > 65 years-old ▪ Concurrent neuro-psychiatric disorders ▪ Recent or current use of psycho-active medication ▪ Suicide attempt or alcoholic coma in the last 3 months.

Mean age of the control group was 51±13 years (range: 22-73 years). 76% were females. Most of the controls originated from urban areas (93%) and 80% had a Bachelor's degree.

There were no significant age-related differences between the two groups (p=0.6).

Disease-related Results

The most common etiology of liver disease was chronic viral hepatitis, which was encountered in 67% of the patients, more specifically hepatitis B virus (HBV) ± hepatitis D virus (HDV) in 37%, and hepatitis C virus (HCV) in 29%, while one patient was diagnosed with all three viruses. Isolated alcoholic liver disease was present in 20% of the patients, however five patients with viral hepatitis were also chronic alcohol consumers. Other causes (e.g. autoimmune hepatitis or primary biliary cholangitis) accounted for 13% of the cases. Mean duration of cirrhosis was 5±5 years (ranging from 0 to 22 years). A history of overt hepatic encephalopathy was noted in 23% of patients. Thrombosis of the portal venous system was present in 25% of cases, while imaging signs of portal hypertension (portosystemic collaterals, umbilical vein recanalization) were described in 89% of patients.

Mean MELD score was 16±6 points, while mean Child-Pugh score was 8±2 points. There was a strong correlation between the two scores (R=0.79, p<0.001). Mean venous ammonia level was 57±33 μmol/L. Mean serum sodium level was 136±5 mmol/L, while mean serum glucose level was 106±35 mg/dL. It is worth mentioning that 24% of the patients were also diagnosed with type II diabetes mellitus.

Stroop Test Results

Mean Stroop results were calculated (Off+On time) for both groups. Stroop test performance of the control group (143.1 ± 20.8 seconds) was significantly better than that of the patient group (171.9 ± 33.3 seconds) (p<0.0001) (Fig. 1).

There was a positive correlation between Stroop test results and patient's age, as calculated using Spearman's rho (R=0.45, p<0.0001). A further stratification revealed a significant difference between patients aged ≤ 50 years (total time: 159.1 ± 31.5 seconds) and patients aged > 50 years (181.5 ± 31.6 seconds) (p=0.0007). The correlation between Stroop test performance and age was stronger for the control group (R=0.75, p<0.0001) (Figs. 2-4).

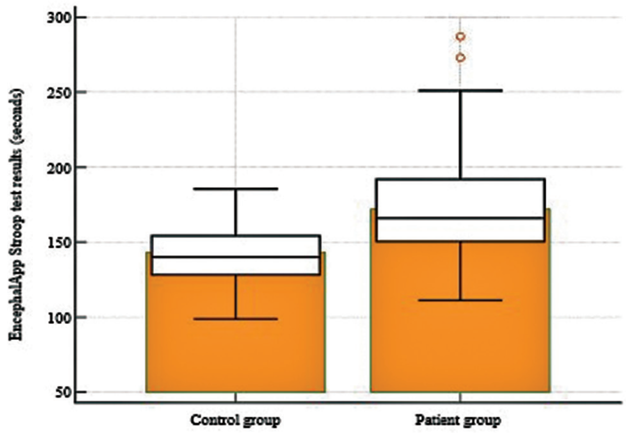

Fig. 1. Participants from the control group performed significantly better than the patients (p<0.0001).

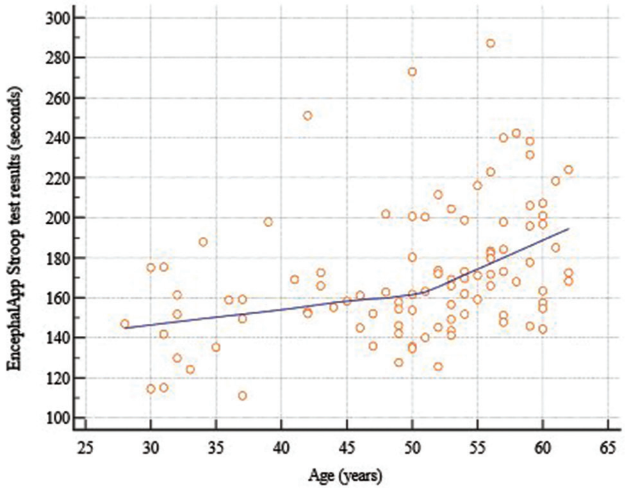

Fig. 2. Positive correlation between EncephalApp Stroop test results and age of the patients (R=0.45, p<0.0001).

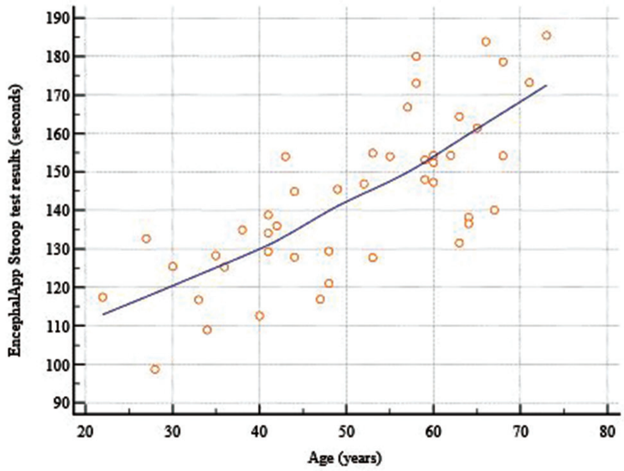

Fig. 3. Positive correlation between EncephalApp Stroop test results and age of controls (R=0.75, p<0.0001).

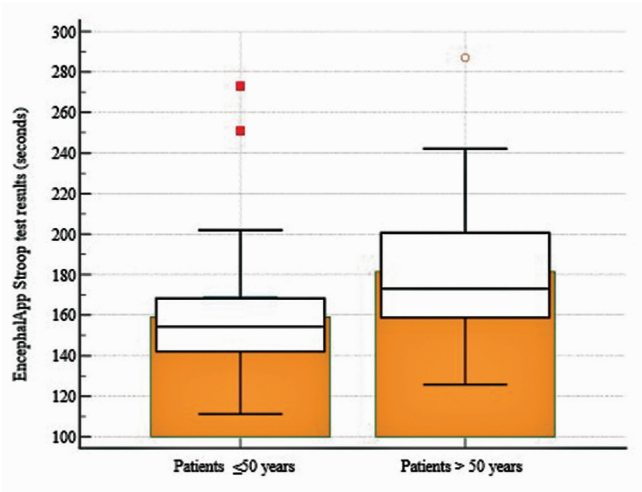

Fig. 4. Patients ≤ 50 years of age performed better than patients > 50 years (p=0.0007).

Based on the available cut-off value of >190 seconds, we diagnosed MHE in 25% of patients.

No significant difference was noted between males and females in either of the groups. In the patient group, Stroop test results in males (171.7 ± 35.0 seconds) and females (172.2 ± 29.5 seconds) were similar (p=0.9). Likewise, no significant difference was noted between males (146.7 ± 24.9 seconds) and females (141.9 ± 19.6 seconds) from the control group (p=0.5). There was no significant difference between patients living in urban areas (170.6 ± 33.0 seconds) and patients living in rural areas (175.3 ± 34.5 seconds) (p=0.5).

Moreover, Stroop test performance was not influenced by education. There was no correlation between test results and the number of years of education in both the patient group (R=-0.04, p=0.7) and the control group (R=-0.26, p=0.08). A further stratification of Stroop test results based on the last level of education completed by the patients (primary education/high school/college) did not reach statistical significance (p=0.1). Mean Stroop time obtained by the primary education graduates was 176.2 ± 39.6 seconds, that of high school graduated was 179.6 ± 36.7 seconds, and that of college graduates was 165.4 ± 27.4 seconds (Fig. 5). The same conclusion was reached for the control-group as well. College graduates from the control group had a mean Stroop time of 140.9 ± 19.8 seconds, while those of lower educational level (high school/primary education) obtained a mean Stroop time of 154.1 ± 24.4 seconds (p=0.1).

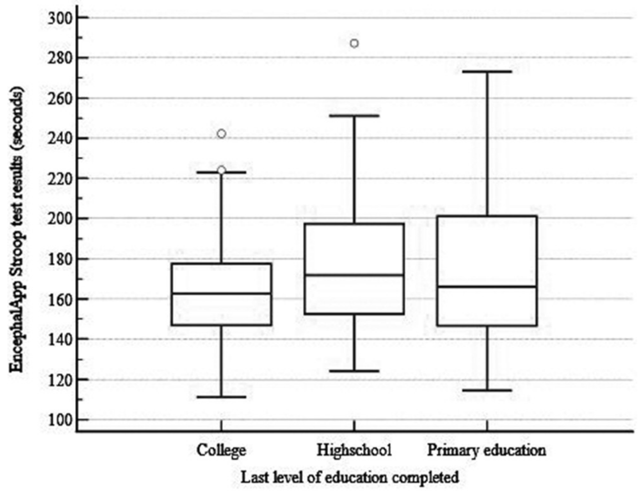

Fig. 5. No statistical significance was noted for Stroop test performance between patients of different educational levels (p=0.1).

Stroop test results correlated with the severity of liver disease as measured using the MELD score (R=0.28, p=0.005) (Fig. 6). The correlation with the Child-Pugh score was weaker (R=0.2, p=0.04). Particularly, patients with compensated cirrhosis (Child-Pugh class A) (157.8 ± 35.4 seconds) performed better than patients with moderate or severe liver dysfunction (Child-Pugh class B or C) (175.0 ± 29.7 seconds) (p=0.04) (Figs. 7, 8).

Patients with alcoholic liver disease performed less well (187.9 ± 38.7 seconds) than patients with cirrhosis due to other etiologies (166.5 ± 29.7 seconds) (p=0.02) (Fig. 9).

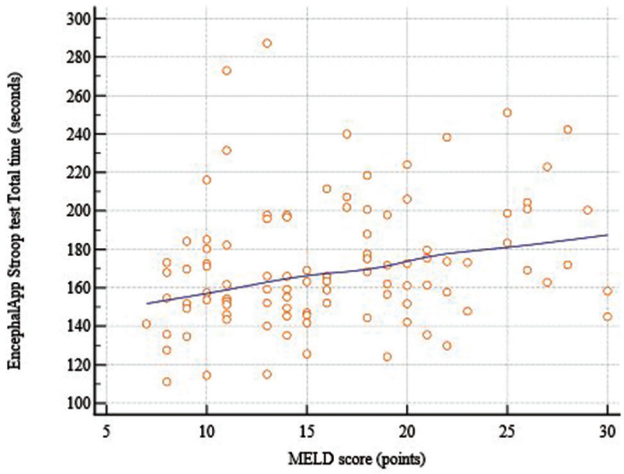

Fig. 6. Negative correlation between EncephalApp Stroop test performance and MELD score (R=0.28, p=0.005).

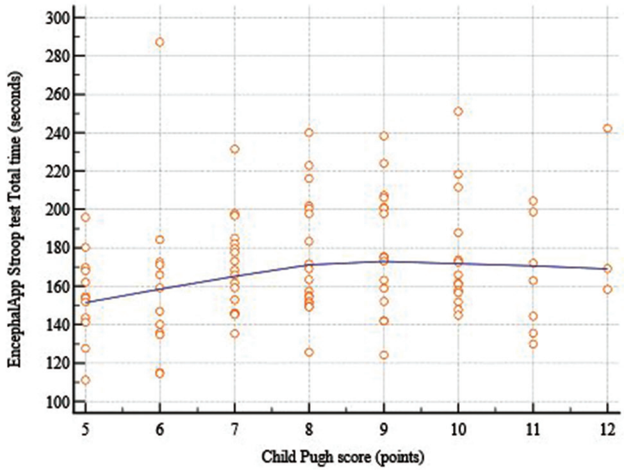

Fig. 7. Negative correlation between EncephalApp Stroop test performance and Child-Pugh score (R=0.2, p=0.04).

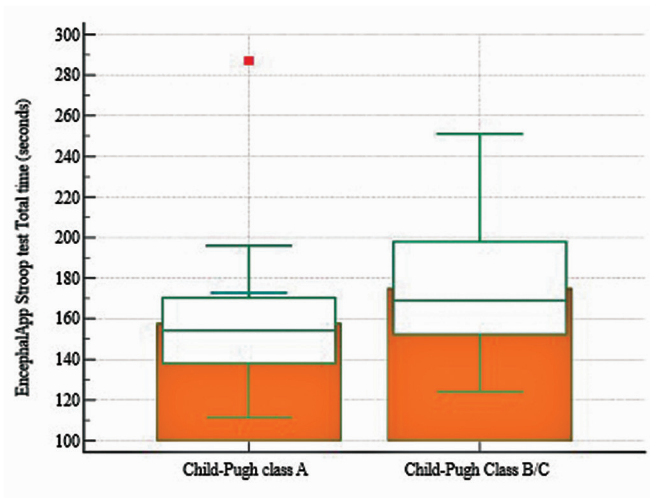

Fig. 8. Patients with Child-Pugh class A performed better than patients with Child-Pugh Class B and C (p=0.04).

There were no significant differences between patients with liver cirrhosis due to HBV±HDV (161.0 ± 29.9 seconds) and those with liver disease due to HCV infection (171.6 ± 31.3 seconds) (p=0.2).

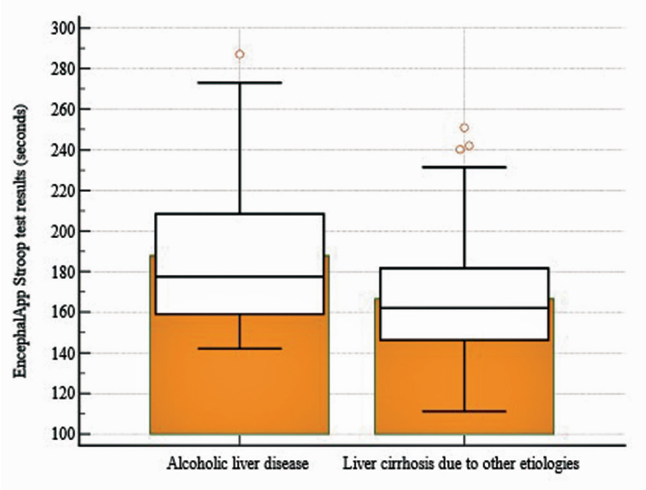

Fig. 9. Patients with alcoholic liver disease performed less well than patients with other causes of liver cirrhosis (p=0.02).

Diabetic patients performed less well (186.9 ± 29.2 seconds) than non-diabetic patients (167.1 ± 33.3 seconds) (p=0.008) (Fig. 10). There was also a positive (albeit weak) correlation between serum glucose levels and Stroop results (R=0.25, p=0.01) (Fig. 11).

Serum sodium levels did not correlate with Stroop test results (R=-0.17, p=0.09). However, patients with normal levels of sodium (166.0 ± 34.5 seconds) performed better than patients with hyponatremia (180.6 ± 30.5 seconds) (p=0.03) (Fig. 12).

Stroop test performance was also influenced by the level of hemoglobin (R=-0.25, p=0.01). Lower levels of hemoglobin (indicating more pronounced anemia) were associated with poorer performances on EncephalApp Stroop test (Fig. 13).

Stroop results did not correlate with blood ammonia levels (R=-0.1, p=0.5). It should be mentioned that venous ammonia levels were also not correlated with liver disease severity, as measured by either the MELD score (R=0.004, p=0.98) or Child-Pugh score (R=0.06, p=0.7). Moreover, there was no difference between patients with normal ammonia levels (as defined by an ammonia level ≤ 54 µmol/L) (mean Stroop time: 170.3 ± 20.3 seconds) and patients with high ammonia levels (mean Stroop time: 176.4 ± 35.5 seconds) (p=0.5).

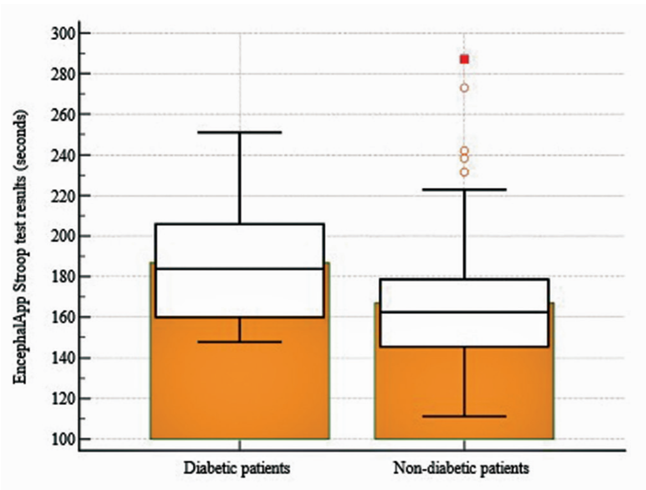

Fig. 10. Diabetic patients performed less well than non-diabetic patients (p=0.008).

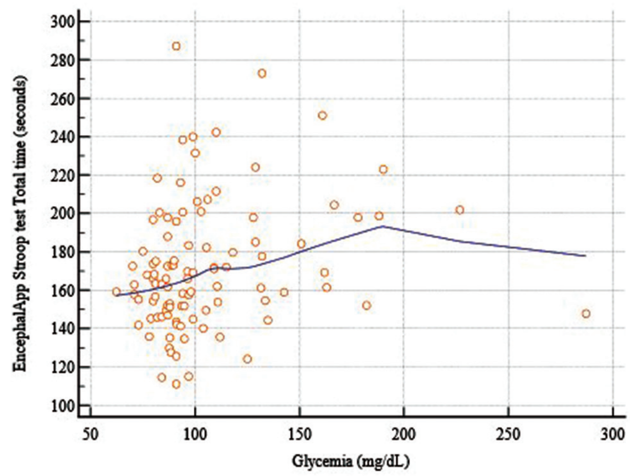

Fig. 11. Negative correlation between Stroop test performance and glycemia (R=0.25, p=0.01).

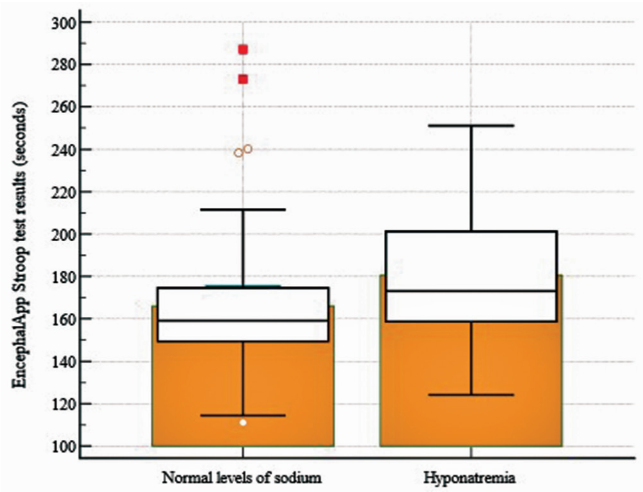

Fig. 12. Patients with hyponatremia performed less well than patients with normal levels of sodium (p=0.03).

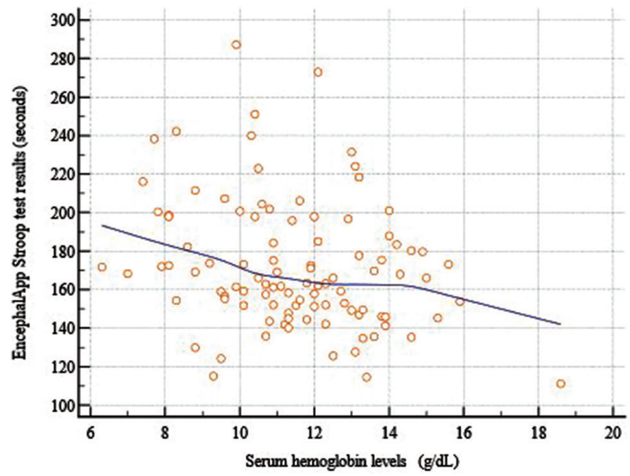

Fig. 13. Lower levels of hemoglobin were associated with poorer Stroop test performance (R=-0.25, p=0.01).

No significant difference was noted between patients with previous episodes of overt HE (177.3 ± 34.4 seconds) and patients without a history of overt HE (167.9 ± 30.8 seconds). However, there was a non-significant trend for the latter category to perform slightly better (p=0.25). Moreover, Stroop test results did not correlate with the duration of cirrhosis (R=-0.08, p=0.4). Patients with thrombosis of the portal venous system (179.4 ± 28.5 seconds) did not perform worse than patients without this condition (168.1 ± 34.2 seconds) (p=0.1). Again, there was a non-significant trend for the latter category to perform slightly better.

DISCUSSION

The EncephalApp Stroop test evaluates the ability to inhibit cognitive interference, i.e. when the processing of a certain characteristic of a stimulus is affected by the simultaneous processing of another characteristic of the same stimulus (inhibitory control or response inhibition) [11].

The app test is composed of two states (Off and On). During the Off state, the patient has to select as fast as possible the name of the color with which a string of four hashes is drawn. During the On state, the patient has to select as fast as possible the name of the color with which another color name is written. Ten such stimuli comprise a test, and each state (Off/On) is composed of five consecutive tests. The total amount of time required to complete all tests is measured (Off+On time).

EncephalApp Stroop Test was initially validated in the USA by Bajaj et al [12]. In the initial assessment, Stroop test performance was weaker in cirrhotic patients with previous episodes of HE, and in patients with MHE diagnosed through other psychometric methods. A cut-off value (Off time plus On time) of > 274.9 seconds was established with a 78% sensibility and 90% specificity. A subsequent study performed by Bajaj et al. [13] established another cut-off value of > 190 seconds as having an area under the receiver operator characteristic (AUROC) of 0.91 for patients with previous episodes of HE and 0.88 for patients without a history of HE. The app was shown to have good test-retest reliability and external validity (in that Stroop test performance improved after correction of hyponatremia and worsened after TIPS placement) [13]. Another study, which compared EncephalApp Stroop test with the Inhibitory control test and Psychometric Hepatic Encephalopathy Score, established that EncephalApp Stroop test has good sensitivity for the diagnosis of MHE and can predict the development of overt HE (independently from the MELD score) [14]. The app has also been used to assess for learning strategies, through the cross-sectional and longitudinal administration of the test, demonstrating that cirrhotic patients with prior episodes of overt HE have persistent learning impairments (which can be reversed after liver transplantation) [15].

EncephalApp Stroop test has been validated in other countries as well [16-19]. Hamzaoui et al. [16] have also emphasized the impact of age on Stroop test performance. Cunha-Silva et al have established a cut-off value of > 269.8 seconds (Off time plus On time) as having 87% sensibility and 77% specificity for the detection of MHE. A cut-off value of 218.3 seconds was determined by Hanai et al. [18] as having the best discriminative ability for MHE diagnosis (sensibility 74%, specificity 75%); however, a value of 305.6 seconds had the best predictive ability for occurrence of overt HE. Zeng et al. [19] defined a cut-off value of > 186.63 (Off time+On time) as having the maximum area-under-the-curve values (0.77). In their paper, Stroop results correlated positively with age and with alcoholic hepatitis (as was the case in our study), but negatively with the duration of education and with patient's experience with electronic devices.

CONCLUSIONS

In our study, EncephalApp Stroop Test proved to be a quick and simple method for diagnosing minimal (subclinical) hepatic encephalopathy in the hospital setting.

Test performance was influenced primarily by age. For this reason, a single cut-off value for the diagnosis of MHE may not be sufficiently accurate, and age-related cut-off values should be established (in patients aged ≤ 50 years and > 50 years). Gender, level of education and patient's settlement of origin (urban versus rural) did not have an impact on Stroop test results.

Test performance was also influenced by liver disease severity (as assessed by the MELD and Child-Pugh scores), as well as by other factors, such as the presence of hyponatremia, anemia and hyperglycemia, although the correlations were weaker than the one with age. Also, patients with alcoholic liver disease performed less well than other cirrhotic patients.

Other factors, such as disease duration, thrombosis of the portal venous system or a history of overt HE did not influence test performance in our study.

Conflicts of interest: The corresponding author, Lupescu Ioan-Cristian, on behalf of all authors of this work, declare that I have received in 2016 material support from SC Alfasigma Romania SRL (in the form of an Apple iPad Mini 4 Cellular 16 GB WiFi 4G) for conducting research on EncephalApp Stroop test and I have received financial support in 2018 from SC Alfasigma Romania SRL for drafting a poster presentation termed "Assessment of subclinical hepatic encephalopathy by using EncephalApp Stroop Test and brain MRI". However, no financial or material support was received regarding the writing and publishing of this article.

Authors' contribution: L.G. conceived and designed the study. I.C.L collected the data, performed the statistical analysis, drafted the manuscript, interpreted the results. S.M.I collected the data, performed the statistical analysis, and interpreted the results. C.P. collected L.G. supervised the study. All authors revised the article, approved the final version to be published and agreed to be accountable for all aspects of the work.

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