HOSPITAL GENERAL de MÉXICO

"Dr. Eduardo Liceaga"

"Clinical trial to evaluate the efficacy of primary prophylaxis with L-ornithine L-aspartate to prevent the development of overt hepatic encephalopathy in patients with cirrhosis and acute variceal bleeding"

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Background

Variceal bleeding (VB) is one of the most important precipitating factors of episodic overt hepatic encephalopathy (OHE). [1]

The intestinal absorption of toxic substances, like the ammonia generated from blood proteins is the main pathophysiologic mechanism for the development of HE following upper gastrointestinal bleeding. [2]

L-ornithine L-aspartate (LOLA), an anti-ammonia therapy, has never been evaluated as primary prophylaxis to prevent the development of OHE in cirrhotic patients after an acute episode of VB.

Objectives

The aim of this study was to evaluate if primary prophylaxis with LOLA is effective to prevent the development of OHE after VB.

Methods

A randomized, double-blind, placebo-controlled clinical trial, approved by Ethics and Research Committees from "***Hospital General de México***", it included cirrhotic patients with VB and without OHE according to West-Haven criteria (WHC), and without minimal hepatic encephalopathy (MHE) assessed by the Psychometric Hepatic Encephalopathy Score (PHES) and critical flicker fusion (CFF) at admission-time.

Sample size was calculated considering a one-tailed 5% type I error, a statistic power of 80%, a difference between groups of 26%, [3] and considering an additional 20% of patients for possible losses.

Group 1 (22 patients) received a 24-hour intravenous infusion of 500ml of 0.9% saline solution containing 10mg of LOLA during 7 days. **Group 2** (22 patients) received placebo.

All patients were daily evaluated searching for signs of OHE according with WHC. Acute VB was treated according with recommendations from Baveno V consensus.

Results

Baseline demographic, clinical and biochemical characteristics of patients

Characteristic	Placebo (n= 22)	LOLA (n= 22)	*P*
Age, years	49.3 ± 9.5	54.3 ± 7.7	0.06
Male, n (%)	17 (77.3)	14 (63.6)	0.32
Child-Pugh A/B/C	5/15/2	7/13/2	0.78
Urea, mg/dL	44.9 ± 22.2	39.5 ± 18.6	0.39
Creatinine, mg/dL	0.9 ± 0.2	0.8 ± 0.2	0.06
Sodium, mEq/L	136.6 ± 3.7	138.2 ± 4.6	0.19
Potassium, mEq/L	3.9 ± 0.4	3.9 ± 0.5	0.89
Chlorine, mEq/L	104.3 ± 6.2	101.9 ± 4.2	0.14
Albumin, mg/dL	2.9 ± 0.7	3.2 ± 0.5	0.11
Bilirubin, mg/dL	2.1 ± 1.8	1.7 ± 1.2	0.34
ALT, UI/L	44.9 ± 30.6	62.9 ± 32.5	0.07
AST, UI/L	57.7 ± 78.9	68.1 ± 39.9	0.98
Alkaline phosphatase, UI/L	104.3 ± 40.2	111.9 ± 39.2	0.53
Gamma glutamyltransferase, UI/L	94.4 ± 79.9	74.8 ± 30.9	0.29
Hemoglobin, g/dL	8.3 ± 2.7	8.6 ± 2.9	0.72
Hematocrit, %	25.7 ± 7.9	26.3 ± 8.3	0.82
Leucocytes, cells/mm³	9.0 ± 5.0	7.5 ± 2.8	0.23
Neutrophils, cells/mm³	6.9 ± 4.6	5.7 ± 2.3	0.25
Platelets, cells/mm³	127.5 ± 71.9	107.2 ± 34.4	024
Protrombin time, sec	16.7 ± 4.0	15.6 ± 3.9	0.37
International Normalized Ratio	1.4 ± 0.3	1.3 ± 0.3	0.28
Etiology of cirrhosis			
Alcohol	11	11	0.28
Hepatitis C	4	4	
Non-alcoholic steatohepatitis	4	7	
Other	3	0	
Transfusion, units	1.4 ± 1.1	1.4 ± 1.2	0.89
Medium Arterial Pressure, mmHg	65.7 ± 10.5	68.4 ± 11.6	0.42
Cardiac frequency, beats/min	94.9 ± 10.4	95.4 ± 12.3	0.87
Time to endoscopy, hours	7.0 ± 1.0	7.0 ± 1.0	1.00
Variceal bleeding source			
Esophageal, n (%)	20 (90.9)	20 (90.9)	1.0
Gastric, n (%)	2 (9.1)	2 (9.1)	
Rebleeding, n (%)	9 (40.9%)	6 (27.3%)	0.34

- Patients in the placebo group had a greater frequency regard to the development of OHE compared with LOLA group (54.5% vs. 22.7%, *P* = 0.03).
- In those who developed OHE, the grade according to WHC was worst in the group receiving placebo (median 3, range 2-4) than in those receiving LOLA (median 1, range 1-2), (*P*= 0.004).
- The time in days for the development of OHE has a median of 2 days (range 1 -4) and 3 days (range 1-3) for placebo and LOLA groups respectively (*P* = 0.65).
- There were no adverse effects or deaths.
- One patient receiving placebo developed spontaneous bacterial peritonitis despite antibiotic prophylaxis, however, he had a good response when antibiotic was adjusted according to the ascites culture result.

Conclusions

- This is the first study that demonstrates that LOLA is an effective therapy for primary prophylaxis in cirrhotic patients with VB to prevent the development of OHE.
- In this study, LOLA also was well tolerated and was free of adverse effects.

References

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Virtual campus in the quality and safety capacitation of pacient care in hospital workers.

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Background

The Hospital General de México "Dr. Eduardo Liceaga", school-hospital par excelence, committed to constantly improve the quality of care of their patients, has implemented the use of Virtual Campus as a strategy to train their medical, paramedical and related, in patients care.

Summary of work

The virtual campus was conducted in moodle platform.

The online course consisted of seven modules in video lessons, which were recorded in hospital channel; subjects were taught by experts with clear and understandable language. This campus was available from May to October 2015.

Each module included a final evaluation, composed of five multiple-choice questions and two opportunities to answer them, requiring a minimum score of 6/10.

Subsequently they underwent a survey to determine the impact of the virtual campus.

Summary of results

We evaluated 129 workers. The topics covered were: obstetric emergencies, Conciliation and Suitability; immunocompromised, treatment and isolation of infecto-contagious, dialysis, neonatal care and comatose patient.

There was 97.52% approval on the first try, getting an average score of 91/100.

In the opinion poll (n=100) of virtual campus, 81.4% agree that access to the virtual campus was easy; 76%, that the content is displayed in a clear way, and finally 93.79% think it worked in everyday life.

Discussion

The use of TICs in the training of personnel is an accessible, user-friendly tool, which produces satisfactory approval ratings in evaluations.

Conclusions

The low cost of the virtual campus allows the entire hospital staff to have access to it. It is also an easy-to-use tool, and helped improving health conditions and patient care with greater user participation.

Take-home messages.

The virtual campus is a good training system for a large population, so we can continue using it in different hospital fields.

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FW: AMEE 2016 - Registration Confirmation

1 mensaje

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