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Modified-orientation log to assess hepatic encephalopathy

M. Salam^{*}, S. Matherly^{*}, I. S. Farooq^{*}, R. T. Stravitz^{*}, R. K. Sterling^{*}, A. J. Sanyal^{*}, D. P. Gibson[†], J. B. Wade[†], L. R. Thacker[‡], D. M. Heuman^{*}, M. Fuchs^{*}, P. Puri^{*}, V. Luketic^{*}, S. J. Bickston^{*}, and J. S. Bajaj^{*}

^{*}Division of Gastroenterology, Hepatology and Nutrition, Virginia Commonwealth University and McGuire VA Medical Center, Richmond, VA, USA

[†]Division of Psychology, Virginia Commonwealth University and McGuire VA Medical Center, Richmond, VA, USA

[‡]Division of Biostatistics, Virginia Commonwealth University and McGuire VA Medical Center, Richmond, VA, USA

SUMMARY

Background—The subjectivity of the West-Haven criteria (WHC) hinders hepatic encephalopathy (HE) evaluation. The new HE classification has emphasised assessment of orientation. The modified-orientation log (MO-log, eight questions, scores 0–24; 24 normal) is adapted from a validated brain injury measure.

Aim—To validate MO-log for HE assessment in cirrhosis.

Methods—Cirrhotics admitted with/without HE were administered MO-log. We collected cirrhosis/HE details, admission/daily MO-logs and WHC (performed by different examiners), time to reach normal mentation (MO-log ≥ 23) and MO-log/WHC change (Δ) over day 1. Outcomes were in-hospital mortality, duration to normal mentation and length-of-stay (LOS). Regressions were performed for each outcome. MO-log inter-rater reliability was measured.

Results—Ninety-six HE (55 ± 8 years, MELD 21) and 20 non-HE (54 ± 5 years, MELD 19) in-patients were included. In HE patients, median admission WHC was 3 (range 1–4). Mean MO-log was 12 ± 8 (range 0–22). Their LOS was 6 ± 5 days and 13% died. Time to reach normal mentation was 2.4 ± 1.7 days. Concurrent validity: there was a significant negative correlation between admission MO-log and WHC ($r = -0.79$, $P < 0.0001$). Discriminant validity: admission MO-logs were significantly lower in those who died (7 vs. 12, $P = 0.03$) and higher in those admitted without HE (23.6 vs. 12, $P < 0.0001$). MO-log improved in 69% on day 1 (Δ MO-log 4 ± 8) which was associated with lower duration to normal mentation (2 vs. 3.5 days, $P = 0.03$) and mortality (3% vs. 43%, $P < 0.0001$), not Δ WHC. Regression models for all outcomes included admission/ Δ MO-log but not WHC as a predictor. Inter-rater reliability: ICC for MO-log inter-rater observations was 0.991.

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Correspondence to: Prof. J. S. Bajaj, Division of Gastroenterology, Hepatology and Nutrition, Virginia Commonwealth University and McGuire VA Medical Center, 1201 Broad Rock Boulevard, Richmond, VA 23249, USA. jsbajaj@vcu.edu.

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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article:

Data S1. Modified orientation log question sheet and script.

Please note: Wiley-Blackwell are not responsible for the content or functionality of any supporting materials supplied by the authors. Any queries (other than missing material) should be directed to the corresponding author for the article.

Conclusions—Modified-orientation log is a valid tool for assessing severity and is better than West-Haven criteria in predicting outcomes in hospitalised hepatic encephalopathy patients.

INTRODUCTION

The assessment of the advanced levels of the spectrum of neuro-cognitive impairment in cirrhosis (SONIC) is difficult given the subjectivity of the current gold standard, the West-Haven criteria (WHC).^{1, 2} This has impeded research, specifically in multi-centre trials, and is a major stumbling block in the assessment of overt hepatic encephalopathy (HE).^{3, 4} In addition, the breadth of the WHC only spans grades 0 through 4, and subtle, day-to-day improvements are difficult to assess and record objectively.⁵ As the grades of HE progress, disorientation becomes an important discriminant. A recent change in the classification highlights the role of disorientation in determining the presence of HE.⁴ However, even eliciting disorientation to time and person, which are the inherent aspects of grade 2 and 3 of the West-Haven criteria, are not standardised. The approach to assess disorientation needs to be uniform to gain full insight into the disease process, guide treatment decisions and compare newer therapies. In addition, an instrument with a wide range to evaluate the depth of disorientation would increase the sensitivity of assessing response to interventions for HE.

The orientation log is a 10-part questionnaire that is validated in the assessment of and predicts outcomes in traumatic brain injury.⁶ It was developed by Novack *et al.* and is freely accessible at <http://www.tbims.org/combi/olog>.⁶ It tests for orientation using a systematic approach that starts with free recall, if that is incorrect, it then goes to a logical cue, failing which a multiple choice option is provided (which gives each question a maximum of three and a minimum of zero points).^{7–9} We modified it to an eight-question instrument by removing questions 9 and 10 that concern brain injury-related specific events and are not relevant for HE. This instrument was termed the modified-orientation log (MO-log). The *a priori* hypothesis was that the MO-log would be valid for disease severity of HE as well as predict outcomes in patients admitted for HE. The aim of the study was to validate the MO-log as an objective method to ascertain the severity of HE and to predict outcomes during a HE-related hospitalisation.

METHODS

Patients admitted with suspected HE to the Virginia Commonwealth University (VCU) Medical Center and McGuire VA Medical Center (VAMC) between July 2010 and September 2011 were administered the MO-log on admission and every day till discharge. Both VCU Medical and VAMC follow a standard protocol for in-patient HE management, which includes investigation and treatment of precipitating factors and initial therapy with lactulose (oral or enema depending on the grade of HE).¹⁰ An additional group of patients with cirrhosis hospitalised for reasons other than HE was also included to study the discriminant validity of MO-log.

The medicine house-staff were trained to perform the MO-log and it was administered using a standard script (supplementary material). The MO-log has eight questions; five on time (year, month, day, date and clock time) and three on place (city, type of place and name of hospital). Each question has a maximum of three points (three points awarded if the answer is received without any cuing, two points if answer given after logical cuing [i.e. for city of Richmond, the logical cue would be 'you are in the capital of Virginia'], 1 point is given if the correct answer picked out of a multiple choice and 0 points if there was no answer or a persistently wrong answer even after the above cues. In the clock time question the scoring is 3 or 0 depending on the answer). At the end of the MO-log, the patients are specifically

told the correct answers. Therefore, the maximum score is 24 and minimum is 0. The total administration time of MO-log can range from 1 to 6 min depending on the degree of disorientation. The utility of MO-log is restricted in patients who are unconscious or those who are not able to verbalize. In patients who are intubated but are able to respond, the maximum score could be seven, as only the multiple-choice questions would be appropriate (without the three points for the clock time).

In this study, the MO-log was administered within 6 h of hospital admission and every day at approximately the same time of day. The West-Haven grade adjudged by another examiner, who was not aware of the MO-log score, was also recorded daily within 3 h of the MO-log administration.

The following data were collected: demographics MELD score, prior episodes of HE, therapy for HE prior to admission, precipitating factors, admission WHC grade (performed by another examiner), sodium and ammonia at admission, length of stay (LOS) and duration before patient regained normal mentation (MO-log 23). Specifically daily MO-logs, maximum MO-log score and time to reach it, and the discharge MO-log score were recorded. Specific patient-oriented outcomes analysed were mortality, duration to normal mentation and total LOS. Duration for normal mentation was considered more important than total LOS since there are several other non-HE reasons for patients staying on in the hospital. Multi-variable regression techniques were used to analyse contribution of the individual variables to these three outcomes.

Concurrent validity was ascertained by correlating admission MO-log score with the WHC grade assigned by an independent examiner using Spearman Rank Correlation. Discriminative validity was determined by comparing mortality, duration to normal mentation and LOS in patients who scores improved in the first 24 h and compared to those whose scores remained similar or worsened for both MO-log and WHC. Discriminant validity was also assessed by performing the MO-log on the patients with cirrhosis admitted for reasons other than HE; their admission MO-logs were compared to those admitted with HE. Inter-rater reliability assessment for MO-log and WHC was performed between two raters who were trained on administration of the MO-log. Both assessed WHC independently prior to administering the MO-log. The MO-log was then administered sequentially within 10 min of the prior administration. Intra-class correlation coefficients were calculated for both questionnaires. *t*-tests were used to compare continuous variables, chi-square and Fisher exact as appropriate were used to compare proportions and nonparametric testing was performed using Kruskal–Wallis tests. A *P* value < 0.05 was considered significant and all data are presented as mean ± standard deviation unless mentioned otherwise.

RESULTS

A total of 96 patients with HE were included (61 from VCU medical centre and 35 from the McGuire VA Medical Center). The mean age was 55 ± 8 years and 82% were men. The mean admission MELD score was 21 ± 8 (median 21). The leading etiologies of cirrhosis were HCV (46%), alcohol (17%), HCV+alcohol (15%) and NASH/cryptogenic cirrhosis (16%). 68% of patients had already had a prior HE episode (median of 1 (range 0–5) episodes. The last episode was a median of 6 weeks (1–48 weeks range) prior to this admission. All patients with prior HE were on lactulose and 54% of them were also on rifaximin.

A precipitating factor was found in 80% of patients; the leading ones were non-adherence to lactulose (42%), sepsis (32%), gastrointestinal bleeding (8%) and dehydration (6%). The

admission venous ammonia was 101.4 ± 53.1 while the sodium value was 133.9 ± 6.9 mg/dL.

The median West Haven grade (analysed by a different examiner) 2 ± 1 h apart, was 3 (range 1–4). The majority of admissions were with grade 3 (42%) or grade 2 HE (40%). Only 16% of patients were admitted in grade 4 and the remaining 2% had grade 1 HE at the time of hospitalisation according to the examiner. The median admission MO-log was 13 (range 0–24). The mean score was 12 ± 8 . There was a significant negative correlation with between admission MO-log and West-Haven scores ($r = -0.79$, $P < 0.00001$, Figure 1). The admission MO-log was statistically similar between those who had had prior HE episodes (12.3 ± 8.3) compared to patients with their first episode (10.1 ± 8.1 , $P = 0.22$). Neither the admission ammonia nor the sodium values correlated with the MO log score or the West-Haven grade.

Patient course

While the majority was admitted to the medical floor, 27% of patients required intensive care unit (ICU) admission. As expected, patients admitted to the ICU had a lower MO-log on admission (7.2 ± 9.2) compared to those who were not (13.3 ± 7.2 , $P = 0.002$), similar for WHC grade in those who were admitted to the ICU (3.2 ± 0.8 vs. 2.6 ± 0.7 , $P = 0.003$). Only five patients admitted to the ICU were intubated and had received sedatives at the time of the first MO-log and WHC assessment. Their initial MO-log scores were near zero because of their inability to respond to questions.

The MO-log improved (i.e. score increased) in 69% of patients over the first day and the mean change was 5 ± 7 points from the baseline ($P < 0.0001$ paired *t*-test). A significantly higher proportion of patients admitted with lactulose noncompliance improved within the first day compared to those admitted with other precipitating factors or with spontaneous HE (45 vs. 22%, $P = 0.026$). The WHC grade improved in 63% of patients over the first day and the median change was 1 (range 0–3 from baseline, $P < 0.0001$).

In-hospital mortality

Thirteen per cent of patients died during their hospitalisation. The mean change over the first day of the MO-log was significantly different in those who died compared to the rest (-1.3 vs. 5.8 , $P = 0.012$) but this was not significant for the change in WHC (0.3 vs. 0.8 , $P = 0.08$). Twelve per cent of the patients who died improved their MO-log within the first day compared to 78% of those who survived the admission ($P < 0.0001$). Conversely, 3% of the patients who improved within the first day died while 43% of those who did not improve died ($P < 0.0001$, Figure 2). The details of patients who died or survived the admission are in Table 1.

Using uni-variate logistic regression, the individual variables significant for prediction of mortality were MELD, admission MO-log, admission WHC, change in MO-log over the first day, duration of stay and age. Using backward elimination, the four variables that remained significant were MELD (OR:1.19, 95% CI:1.05–1.34, $P = 0.006$), Change in MO-log first day (OR:1.29, 95% CI:1.06–1.56, $P = 0.012$), admission MO-log (OR:0.86, 95% CI:0.76–0.96, $P = 0.009$) and age (OR:1.16, 95% CI:1.00–1.33, $P = 0.043$).

Time to reach normal mentation

The majority of patients (85%) reached normal mentation; the rest died or were discharged to hospice. The mean LOS was 6.3 ± 4.9 days but the time to normal mentation was only 2.4 ± 1.7 days, which highlights reasons other than HE improvement that can increase total LOS. This duration was not significantly correlated with age or gender, but was significantly

related to admission MO-log ($r = -0.4$, $P = 0.003$) and WHC ($r = 0.31$, $P = 0.009$). This time period was significantly lower in those who improved their MO-log over day 1 ($P = 0.03$) but not in those with improved WHC ($P = 0.46$). On univariate regression, when WHC itself was used, it only explained 5%, while when MO-log admission and improvement on day 1 were considered; they explained 35% of the variance. Multi-variable regression analysis showed that the duration to reach normal mentation was predicted by admission MO-log ($P < 0.0001$), change in MO-log over day 1 ($P < 0.0001$), MELD score on admission ($P < 0.05$) and admission sodium ($P = 0.12$) which explained 57.23% of the variance.

Comparison with patients without HE on admission

The MO-log was also administered to an additional 20 cirrhotic patients without HE as the cause of their admission who had similar age and MELD scores to those in the HE cohort (age 54 ± 5 years, 16 men, MELD 19 ± 8 , 8 from VAMC and 12 from VCU Medical Center). Similar to those admitted with HE, the majority had HCV ($n = 14$), followed by alcohol alone ($n = 3$) and both HCV and alcohol ($n = 3$). Six patients had experienced HE prior to this hospitalisation and were controlled on lactulose at the time of and throughout the hospitalisation. The reason for admission was abdominal distension and pain in six, bleeding in five, management of oedema in four, severe anaemia in two and renal failure in three patients. The mean MO-log on admission was 23.6 ± 0.6 (median 24); 14 had a score of 24 and the rest were 23. This MO-log score was significantly higher compared to patients admitted with HE (23.6 vs. 12.0 , $P < 0.0001$). All patients were scored as zero on WHC on admission, which was also significantly lower than the WH score in those admitted with HE (median 0 vs. 3, $P < 0.0001$). The mean LOS was 6 ± 5 days, three patients were initially admitted to the ICU and none of the patients died during the admission. The change in MO-log (23.6 compared to 23.9) or WHC (0 vs. 0) over the first day was not statistically significant since most patients were near perfect scores to begin with and all patients maintained a MO-log score of 23 till discharge.

Total LOS

This was correlated significantly to admission MO-log ($r = -0.3$, $P = 0.007$) and WHC ($r = 0.26$, $P = 0.012$). The LOS was also significantly lower in patients admitted with lactulose noncompliance compared to other precipitating factors (4.8 ± 3.7 vs. 7.2 ± 5.3 days, $P = 0.013$). The regression analysis included admission laboratory values, WHC and MO-log and change over day 1, lactulose noncompliance and age. The model that explained the most variance (34.99%) consisted of admission MO-log ($P < 0.0001$), change in MO-log over day 1 ($P = 0.001$), lactulose noncompliance ($P = 0.03$), admission ammonia ($P = 0.03$), age ($P = 0.03$) and MELD ($P = 0.12$).

Lactulose noncompliance

This was the most common precipitating factor in our population. Interestingly, the admission MO-log was not different between patients admitted with and without lactulose noncompliance (11.9 ± 8.4 vs. 11.1 ± 8.1 , $P = 0.66$) but the change in MO-log over day 1 was significantly higher in those with lactulose noncompliance compared to other precipitating factors (6.9 vs. 3.8 , $P = 0.05$). Importantly, outcomes such as LOS ($P = 0.013$), mortality (0% vs. 20%, $P < 0.0001$), and ICU stay (12 vs. 36%, $P = 0.014$) were significantly better in this population. This again highlights the importance of the precipitating factor as a determinant of outcomes.

Inter-rater reliability

MO-log and WHC were rated twice in 25 patients admitted with HE. The average MO-log of the first examiner was 17.1 ± 5.9 compared to the second examiner's 17.2 ± 5.8 . The ICC

was 0.991 (95% CI: 0.980–0.996). The mean WHC by both examiners was 2 but the ICC was lower at 0.730 with a comparatively wider confidence interval compared to the MO-log (95% CI: 0.478–0.872).

DISCUSSION

The current study shows that the simple MO-log shows good concurrent and discriminant validity and inter-rater reliability. Admission MO-log and change in MO-log over the first day of hospitalisation was able to predict mortality and time to reach normal mentation during the admission, unlike WHC on regression analyses. MO-log scores were significantly better in patients admitted for reasons other than HE compared to those admitted with HE.

The SONIC encompasses impairments in cognition, sensorium and neurological function.¹ However, the routine characterisation of all these aspects in every patient with suspected HE is neither practical nor even necessary to guide therapeutic decisions.¹¹ Therefore, the currently available gold standard, the West-haven criteria are used. However, these criteria are often subjective and are limited to four grades that make them very difficult to interpret across centres and observers. In fact the recent re-classification of HE excludes grade 1 of WHC from HE because of the subjectivity and restricts the diagnosis of overt HE to patients who have demonstrable disorientation. The clinical diagnosis of HE is usually made when patients are disoriented, most often to time-related queries in grade 2 and to place and then person in grade 3 of the WHC.¹² For this reason, the analysis of disorientation needs to be uniform. In clinical practice, the assessment of orientation is through a series of questions with categorical results, that is, the patient is either able to tell you the exact time or place or is not able to. This approach does not differentiate between subjects who are off by 1 day from those who are wrong by several months. As a result, it cannot explore the depths of disorientation and may reduce its reproducibility across centres. Therefore, we chose the MO-log, which breaks down disorientation to time and place into four intuitive levels scored in order of worsening mental function. This increases the spread of the scores to be sensitive to subtle changes in orientation over days and after therapy. An approach relying on the use of orientation to time was useful in older subjects.¹³

The concurrent and discriminative validity of the MO-log assessment was demonstrated by the significant negative correlation between MO-log and admission WHC, the significantly lower MO-log score of those admitted to the ICU instead of regular floors, relationship of MO-log to mortality and the significant difference in MO-log scores in patients who were admitted without HE to those who had HE. It is also interesting that the change in MO-log scores over the first day predicted mortality. This is likely because the precipitating factors are usually confirmed and treatment is initiated within the first day post-admission.⁵ The leading precipitating factor was noncompliance with lactulose, which was readily corrected since the admission protocol includes lactulose therapy.¹⁰ Corroborating this, we also found that a significantly higher proportion of patients admitted with lactulose noncompliance improved their MO-log within the first day compared to the rest, had a lower LOS and time to normal mentation. This may have influenced the correlation between the LOS and improvement over the first day in the MO-log score. As the correct answers were told to the patients at the end of the testing, it is also possible that patients with lesser degree of disorientation were able to learn and remember those responses and consequently improve over the first day. Conversely, it is equally important to realise that the group that did not improve their MO-log over the first day remained that way despite being told the correct answers on the prior MO-log administrations. The learning difficulties associated with HE have already been demonstrated in other studies.^{14, 15}

We also found a significant inter-observer reliability for the MO-log, which was higher than that of the WHC; this is probably due to a script that is created for the MO-log which standardises the questions and their responses compared to WHC in which each centre and individual may have their own method of delineating the grade. This again highlights the imperfect and subjective nature of WHC that is prevalent in assessing HE as standard of care.

In-hospital mortality was predicted by change in MO-log scores, which signify worsening neuro-cognitive status. The patients who died were likely to have a precipitating factor other than lactulose noncompliance, had worse disorientation on exam and poor response to the HE protocol within the first day. This indicates that the MO-log is responsive to changes in the underlying status of the patients and its direction of change can give us good prognostic information. It is interesting to note that the WHC change over the first day did not affect LOS or mortality in contrast to MO-log. This is likely because of the limited range that the WHC has compared to the MO-log and maybe due to its subjectivity. The regression analyses for mortality, LOS and duration to gain normal mentation consistently had MO-log and change in MO-log over day 1 instead of WHC grade and change. This is an indication that a reliable and consistent approach to analysing orientation may be superior to the status quo in predicting important outcomes in patients admitted with HE.

There have been several studies to improve the assessment of HE in research as well as clinical settings. The Hepatic Encephalopathy Scoring Algorithm (HESA) is a compendium of cognitive tests and clinical examinations that fits patients into the pre-existing WHC.^{16–18} This has been used in several clinical trials; however, it requires time and expertise to administer.^{17, 18} Therefore it is not practical for routine use in HE assessment. Amodio *et al.* have proposed a modification of the WHC that adds the Number Connection Test-A and animal naming as part of grade 1, used disorientation to time as grade 2 and disorientation to place as grade 3.¹² Although this modification has not specifically been validated, this is in line with the focus on disorientation as a key differentiator between HE stages.¹² The Clinical Hepatic Encephalopathy Staging scale (CHESS) was developed for evaluating advanced HE stages in in-patients and it consists of nine questions that inquire about orientation as well as response to commands and speech patterns.¹⁹ While it is simple to use, some questions in the CHESS can be interpreted subjectively, that is, ‘can the patient speak clearly’ and it has not been validated outside Spain.¹⁹ Both the CHESS and Amodio modification of the WHC have questions that result in categorical answers and do not further investigate the quality or severity of disorientation. The MO-log, building on these outlines, rapidly evaluates the depth of disorientation to time and place in a standardised manner and is able to predict course of illness.

These results need to be validated in a larger population, specifically to clarify the contribution of specific treatment strategies on illness course. Like most orientation questionnaires, MO-log is not specific for HE as it was initially validated in traumatic brain injury and will not be able to ascertain the cause of disorientation. However, we were able to demonstrate that in a similar population with cirrhosis admitted without HE, the MO-log was significantly better than those who were admitted with HE, indicating its sensitivity and discriminant validity. We did not study outcomes beyond the hospitalisation in this study. The use of other objective markers, such as EEG could have improved the assessment of HE severity at baseline. However, the goal of this study was to mirror real-life situations in which the questionnaire-based assessment determines the severity of HE and therefore WHC, the existing standard of care was employed. Orientation is only one aspect of the multiple neuro-cognitive issues that occur in SONIC.^{1, 11} Therefore, relying on an orientation questionnaire alone may miss the other facets of SONIC. The MO-log, however, presents with several practical advantages over the WHC in that it is standardised,

objectively scored, relatively simple to administer, provides a greater spread of scores to identify change direction in a sensitive manner and in the future could also be potentially administered by nursing staff if found to be validated in other studies.

We conclude that the MO-log, a simple eight-question layered assessment of disorientation to time and place has good concurrent validity, discriminant validity and inter-rater reliability in patients hospitalised with HE. MO-log scores can differentiate between cirrhotic patients who were admitted with and without HE. The direction and extent of improvement in MO-log over the first day of admission can predict in-hospital mortality, time needed to regain normal mentation and LOS in direct comparison and on regression analyses. Further studies with MO-log are needed to validate these findings in larger populations.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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Figure 1.

Comparison of the admission West-Haven grade with the modified-orientation (MO)-log scores. There was a significant negative correlation between the admission MO-log and West-Haven grade of HE; 0 is the worst and 24 is the best performance on MO-log ($r = -0.79$, $P < 0.0001$). The West-Haven grades and MO-logs were assigned by different examiners.

Figure 2.

Differences in mortality between those who improve their modified-orientation (MO)-log score within the first day of admission compared to those who do not. Mortality was significantly higher in those who did not improve compared to those who improved MO-log within the first day of admission.

Table 1

Comparison of patients who died or survived the admission for HE

	Died during the admission (<i>n</i> = 15)	Survived the admission (<i>n</i> = 81)	<i>P</i> value
Age	56.4 ± 9.6	55.0 ± 7.6	0.634
Noncompliance as a precipitating factor	0%	40%	0.006
Admission MELD	30.0 ± 9.7	19.3 ± 6.9	0.003
Admission serum sodium	135.3 ± 10.8	133.6 ± 6.3	0.62
Admission venous ammonia	88.7 ± 56.4	103.4 ± 52.8	0.49
Admission WHC	3.3 ± 0.8	2.6 ± 0.7	0.019
Admission MO-log	4.3 ± 7.5	12.1 ± 8.1	0.016
Change in MO-log over the first day	-1.3 ± 7.5	5.8 ± 6.9	0.012
Improvement in MO-log over day 1	12%	78%	<0.0001
Change in WHC over day 1	0.3 ± 0.7	0.8 ± 0.8	0.08
Improvement in WHC over day 1	50%	64%	0.24
Length of stay	10.2 ± 6.1	5.8 ± 4.5	0.041

WHC, West-Haven criteria; HE, hepatic encephalopathy.

Patients who died during the admission were more likely to have advanced MELD scores, higher WHC, grade, lower admission modified-orientation (MO)-log scores, worse recovery within the first day as well as a precipitating factor other than lactulose noncompliance. *t*-tests, Fisher exact and chi-square tests were used as appropriate.