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ORIGINAL ARTICLE

Availability of PEth testing is associated with reduced eligibility for liver transplant among patients with alcohol-related liver disease

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Abstract

Background: Serum phosphatidylethanol (PEth) is a highly sensitive test to detect alcohol use. We evaluated whether the availability of PEth testing impacted rates of liver transplant evaluation terminations and delistings.

Methods: Medical record data were collected for patients who initiated transplant evaluation due to alcohol-related liver disease in the pre-PEth (2017) or PEth (2019) eras. Inverse probability weighting (IPW) was used to balance baseline patient characteristics. Outcomes included termination of evaluation or delisting due to alcohol use; patients were censored at receipt of transplant; death was considered a competing risk. The Fine-Gray method was performed to determine whether PEth testing affected risk of evaluation termination/ delisting due to alcohol use.

Results: Three hundred and seventy-five patients with alcohol-related indications for transplant (157 in 2017; 210 in 2019) were included. The final IPW-adjusted model for the composite outcome of terminations/delisting due to alcohol use retained two significant variables ($P < .05$): PEth era and BMI category. Patients evaluated during the PEth era were almost three times more likely to experience an alcohol-related termination/delisting than those in the pre-PEth era (sHR = 2.86; 95%CI 1.67–4.97)

Conclusion: We found that availability of PEth testing at our institution was associated with a higher rate of exclusion of patients from eligibility for liver transplant. Use of PEth testing has significant potential to inform decisions regarding transplant candidacy for patients with alcohol-related liver disease.

KEYWORDS
alcoholic liver disease, delisting, evaluation termination, liver transplantation, PEth, phosphatidyl ethanol, waitlist outcomes

1 INTRODUCTION

Alcohol (ethanol) is one of the most common causes of chronic liver disease.[1] Alcohol-related liver disease causes roughly half of all cirrhosis worldwide; a recent report noted that alcohol-related cirrhosis was responsible for 21% of orthotopic liver transplants in the United States.[2,3] In the past, many liver transplant programs in the United States required patients with alcohol-related cirrhosis to fulfill a “six-month rule” of abstinence from alcohol.[3] More recently, however, many transplant programs have adopted policies of evaluating transplant candidates on a “case-by-case” basis, allowing patients with alcohol-related hepatitis and recent alcohol use to be considered for transplant.[4] This has expanded the pool of patients with alcohol-related liver disease being considered for transplant. Accurate assessment of alcohol use has therefore become imperative.

Studies have shown that serum measures of phosphatidylethanol (PEth)—a group of phospholipids formed only in the presence of ethanol via the action of phospholipase D—can identify recent alcohol use with high sensitivity and specificity; with a half-life of 4.5–12 days, PEth can be detected in blood for 3–4 weeks after alcohol ingestion.[5–7] This contrasts with other blood and urine alcohol detection tests such as blood alcohol concentration, ethyl glucuronide, ethyl sulfate, and carbohydrate-deficient transferrin, which can detect alcohol use only from several hours to 1 week after consumption.[8] This feature of PEth has led to its wide utilization in various clinical settings for the detection of alcohol use, including in the liver transplant setting.

Only a few small studies have assessed the use of PEth in the context of patient evaluation for liver transplant; these have demonstrated the ability of PEth to accurately assess alcohol use in patients pre- and post-transplant.[9–11] However, there is little data regarding the impact of PEth testing on transplant decisions and outcomes. In this study, we sought to determine whether rates of transplant evaluation terminations and delistings among patients with alcohol-related liver disease differed in the pre-PEth versus PEth eras.

2 METHODS

The study was designed as a retrospective cohort of liver transplant patients at Henry Ford Health System (HFHS), a large tertiary health system in metropolitan Detroit, MI, USA. All study protocols were approved by the HFHS Institutional Review Board; given the observational and de-identified nature of the data, the requirement for signed informed consent was waived. The study included transplant evaluations listed in the Organ Transplant Tracking Record that were initiated between 1/1/2017 and 11/12/2019; evaluations initiated in the 2018 calendar year were excluded, therefore creating an exclusively pre-PEth era (2017) and PEth era (2019).

Patients were considered if they had any component of alcohol-related liver disease (e.g., alcohol alone or alcohol in combination with hepatitis C infection) and initiated evaluation for liver transplant during the two eras; patients with all other etiologies were excluded. Within our health system, all transplant candidates with alcohol-related liver disease are evaluated by a transplant psychologist. Patients receive individual counseling about the necessity of permanent discontinuation of alcohol use and are required to enroll in an alcohol relapse prevention program. They are informed that they will be tested for alcohol use at the beginning of the evaluation and may be tested intermittently prior to transplant; testing may be random, due to clinical deterioration, or suspicion of resumed alcohol use. In 2017, blood or urine alcohol testing was used; after PEth testing was introduced, other methods of testing were discontinued. Finally, patients sign a contract confirming they understand our institution’s policies. At the time of this analysis (2017–2019), HFHS had a “zero tolerance” policy for use of alcohol during the evaluation period and while on the transplant waitlist; a positive test for alcohol use resulted in termination of the transplant evaluation or removal from the waitlist, without future opportunities to be considered for transplant at our institution. The option for status 7/temporary inactive list was not used for a positive alcohol result; all evaluation terminations/delistings due to alcohol use were final.

Data were collected from individual patient electronic medical records, which included provider and transplant coordinator notes, Transplant Committee letters sent to patients, laboratory testing results, and imaging. Basic patient data included age, sex, race/ ethnicity (categorized as Black/African American, white, Asian American/ Pacific Islander [AAPI]/Other, and Hispanic [of any race]), and body mass index (BMI). Presence of comorbidities—including diabetes, hypertension, dyslipidemia, myocardial infarction, stroke, chronic kidney disease, and hepatocellular carcinoma—were recorded. Additional data collected included whether liver disease was due to cirrhosis or alcoholic-related hepatitis; PEth and non-PEth (serum ethanol or ethyl glucuronide) alcohol test results; reported alcohol use; Child-Pugh and Model For End-Stage Liver Disease (MELD) scores at initiation of evaluation; and dates of initiation/ termination of transplant evaluation, placement on a transplant waiting list (listing), removal from waiting list (delisting), receipt of transplant, and/or death. Positive PEth was defined as > 10 ng/dl.[12] Reasons for evaluation termination or delisting were documented as well, and included positive PEth/ non-PEth testing, reported alcohol use, non-alcohol substance use, prohibitive medical status, psychosocial concerns, need for completion of relapse prevention, patient preference, stable disease, patient enrolled in hospice, and insurance issues. Household income was estimated based on US Census block group median household income mapped to patients’ home addresses.

Patients were followed from initiation of transplant evaluation until termination of evaluation (without listing), delisting, receipt of transplant, or death. Placement on the transplant list was defined as an acceptance letter from the Transplant Committee in the medical record and registration in the United Network of Organ Sharing registry. Evaluation termination was determined to occur if a patient underwent transplant evaluation initiation, was not listed for transplant, and received a letter notifying them of conclusion of their evaluation, excluding those who died during their evaluation. Delisting was determined to occur if a patient completed evaluation, was listed for transplant, and received a letter notifying them of removal from the transplant list, excluding those who received a transplant or died while listed.

The outcome of interest was a composite outcome of evaluation termination due to alcohol use or delisting due to alcohol use. "Alcohol use" as a reason for evaluation termination or delisting was determined by testing (blood or urine testing in 2017; PEth in 2019) or reported alcohol use. Patients who received a transplant were censored at the date of receipt. Death was considered a competing risk.

2.1 | Statistical analysis

Patients were followed from initiation of transplant evaluation until receipt of transplant, death, termination of evaluation, delisting, or March 9, 2020, whichever was earliest. Inverse Probability Weighting (IPW) was used to adjust for differences in the following baseline patient characteristics between the samples of patients evaluated in the pre-PEth and PEth eras: variables included: year transplant evaluation was initiated; sex; type of insurance; median household income; employment status; and marital status. Comparisons between pre-PEth and PEth eras were carried out using Chi-square tests for categorical variables and t-tests for continuous variables. The effect of era (pre-PEth vs. PEth) on risk of the composite outcome (evaluation termination / delisting due to alcohol use) was tested using competing risk analysis (Fine-Gray subdistribution hazard ratio method), adjusted for IPW weights and with death considered as a competing risk. Censoring occurred if the patient received a transplant, their evaluation was terminated, or they were delisted for reasons other than alcohol use. In addition to year of evaluation initiation (PEth era) variables used in the model included: race/ ethnicity, sex, BMI category (< 18.5, $18.5 < 25$, $25 < 30$, and ≥ 30); Child-Pugh score; MELD score; type of insurance; median household income; employment status; and marital status. Stepwise backward elimination was used to determine the final model; variables that yielded *P*-values $< .05$ were retained in the final model.

3 | RESULTS

Patient characteristics are shown in Table 1. A total of 375 patients had alcohol-related indications for liver transplant in the years of interest (157 in 2017 [pre-PEth] and 210 in 2019 [PEth]); eight patients were excluded due to lack of follow-up data after evaluation initiation. There were 357 patients with alcohol-related cirrhosis, 29 patients with alcohol-related hepatitis, and one patient with alcohol-related hepatitis superimposed upon alcohol-related cirrhosis. The majority of patients in both eras were white (90% and 84% in 2017 and 2019, respectively) and male (67% vs. 68%). Mean MELD-Na scores were significantly higher in the PEth era (23.9 ± 10.0 vs. 20.3 ± 7.7; $P < .001$) as were the number of patients classified as Child-Pugh Class C (58% vs. 49%).

Table 2 presents the outcomes of the included patients during follow-up. There were 72 evaluation terminations of patients whose evaluation was initiated in the pre-PEth era, seven of which (10%) were due to alcohol use, and 85 evaluation terminations of patients whose evaluation was initiated in the PEth era, 17 of which (20%) were due to alcohol use. Seventy-one of the pre-PEth era patients were placed on the transplant list, 11 of whom (16%) were delisted; three of these (27%) were for alcohol use, two of which were detected with testing. Fifty-nine of the PEth era patients were listed for transplants; two (3%) were delisted, both (100%) due to alcohol use detected with testing. Of the delistings/terminations, there were a total of five (7%) for positive urine/serum alcohol tests in 2017 versus 16 (19%) for positive PEth tests in 2019. Among the pre-PEth era patients, 30/157 (19%) died during evaluation, 6/71 (8%) died while listed and 49 received transplants. Among the PEth era patients, 50/210 died during evaluation, 1/59 died while listed, and 38 received transplants.

After IPW-weighting, patient characteristics were balanced between the two eras (standard difference $< .2$). Figure 1 illustrates the cumulative incidence curves of the composite outcome (terminations/ delistings due to alcohol use) stratified by PEth era. The final IPW-adjusted Fine-Gray model retained two significant variables ($P < .05$): PEth era and BMI category (Table 3). Patients that initiated transplant evaluation during the PEth era (2019) were almost three times more likely to experience an alcohol-related termination/delisting than those who initiated evaluation during the pre-PEth era (Fine-Gray subdistribution Hazard Ratio (sHR) = 2.86; 95% Confidence Interval (CI) 1.67–4.97). In addition, patients with BMI 25–30 were less likely to experience evaluation termination or delisting due to alcohol use than those with BMI $18.5 < 25$ (sHR = .40; 95%CI .18–.90).

We also performed a sensitivity analysis that used evaluation terminations due to alcohol use (without delistings) as the outcome of interest. Results were consistent with that of the main analysis (Supplemental table 1).

4 | DISCUSSION

The present study assessed the clinical impact of PEth testing on the liver transplant process as it relates to rates of evaluation termination and delisting due to alcohol use. After using IPW to adjust for baseline differences, we found that PEth era and BMI were associated with risk of termination/ delisting due to alcohol use using survival analyses that included death as a competing risk. In 2019, patients who initiated transplant evaluations were at almost three times higher risk of transplant evaluation terminations/ delistings due to alcohol use compared to those who initiated evaluations in 2017, before the adoption of routine PEth testing of transplant candidates.

In general, the results of our multivariable analysis reflect factors known to be related to likelihood of achieving a transplant. Although it is not clear why patients with BMI $25 < 30$ were less likely than those with BMI $18.5 < 25$ to be terminated/ delisted, it is possible that patients with lower BMI may be experiencing inappetence, weight loss, and frailty and in overall poorer health.[13,14] Interestingly, data has shown than beyond a BMI of 30, the risk of alcohol-related liver

TABLE 1 Univariate comparison of patient characteristics for the pre-PEth and PEth testing eras

Variable	Response	2017 ($N = 157$)	2019 ($N = 210$)	Test statistic* value	*P*-value
Race	Black/ African American	13 (8%)	19 (9%)	5.72	.129
	Hispanic (any race)	3 (2%)	9 (4%)		
	White	141 (90%)	177 (84%)		
	AAPI/ Other	0 (0%)	5 (2%)		
Sex	Male	105 (67%)	142 (68%)	.014	.881
	Female	52 (33%)	68 (32%)		
Median household income	<40k	40 (25%)	131 (63%)	53.05	<.001
	40–60k	58 (37%)	35 (17%)		
	60–80k	41 (26%)	29 (14%)		
	80–100k	9 (6%)	11 (5%)		
	>100k	9 (6%)	3 (1%)		
Employment status	Employed	41 (26%)	54 (26%)	.14	.931
	Not employed	107 (68%)	141 (67%)		
	Unknown	9 (6%)	14 (7%)		
Insurance status	Medicare/ Medicaid	78 (50%)	125 (60%)	7.21	.027
	Private	76 (48%)	83 (39%)		
	Other / None	3 (2%)	2 (1%)		
Marital status	Married	80 (51%)	95 (46%)	1.38	.502
	Single/ Widowed/ Divorced	60 (38%)	83 (40%)		
	Significant other	16 (10%)	28 (14%)		
BMI category	<18.5	5 (3%)	6 (3%)	.039	.998
	18.5- < 25	45 (29%)	60 (29%)		
	25-30	53 (34%)	70 (33%)		
	30 or higher	54 (34%)	73 (35%)		
MELD	Mean ±SD	16.0 ± 8.1	20.8 ± 11.1	-4.85	<.001
MELD-Na	Mean ±SD	20.3 ± 7.7	23.9 ± 10.0	-3.92	<.001
Child-Pugh	Class A	4 (3%)	5 (3%)	2.90	.257
	Class B	73 (49%)	77 (40%)		
	Class C	73 (49%)	111 (58%)		

*Test statistic: T-statistic for continuous variables; Chi-square for categorical variables.
Abbreviations: BMI, body mass index; MELD, Model for End-Stage Liver Disease; MELD-Na, Model for End-Stage Liver Disease with sodium levels; SD, standard deviation.

disease actually increases likely due to the synergistic effect of obesity and heavy alcohol use.[15]

There is limited data addressing delisting due to laboratory testing to detect alcohol use. In a 2010 article, Carbonneau et al.[16] reported a pre-transplant delisting rate of 17% due to alcohol use as detected by random blood alcohol levels. This was a significant increase from a 5% delisting rate prior to the implementation of blood alcohol testing. Notably, although the delisting rate in that study was higher than expected despite an extensive psychosocial evaluation, participation in rehabilitation program, and regular office visits, it was felt to be in range with prior estimates of post-transplant relapse. This further emphasizes the need for regular, accurate testing for alcohol use given the prevalence of relapse both prior to and following transplant. Several studies have demonstrated the increased sensitivity and specificity of PEth as compared to non-PEth alcohol tests such as ethyl glucuronide and ethyl sulphate, in both the transplant and non-transplant settings.[6,9–11] Additionally, the longer half-life of PEth has allowed for its detection up to a month following alcohol use, unlike other alcohol tests which are typically detected no longer than a week after alcohol use. Finally, its quantitative property allows the differentiation of light, moderate, and heavy alcohol use, which may be helpful for diagnostic purposes when attempting to determine the etiology of liver disease (e.g., when attempting to distinguish between hepatitis due to heavy alcohol use versus decompensated liver disease of alternate etiology with light background alcohol use).

TABLE 2 Patients with alcohol-related indications for transplant in the pre-PEth (2017) and post-PEth (2019) eras

	2017	2019
Evaluated	157	210
Evaluation terminated for any reason	72 (46% of evaluations)	85 (40% of evaluations)
Terminated due to any alcohol use	7 (10% of terminations)	17 (20% of terminations)
Terminated due to alcohol use identified by testing	5 (71% of alcohol terminations)	16 (94% of alcohol terminations)
Died during evaluation period	30	50
Placed on transplant list	71	59
Delisted for any reason	11 (16% of listed patients)	2 (3% of listed patients)
Delisted due to alcohol use	3 (27% of delisted patients)	2 (100% of delisted patients)
Delisted due to alcohol use identified by testing	2 (18% of delisted patients)	2 (100% of delisted patients)
Died before receiving transplant	6	1
Received transplant	49	38

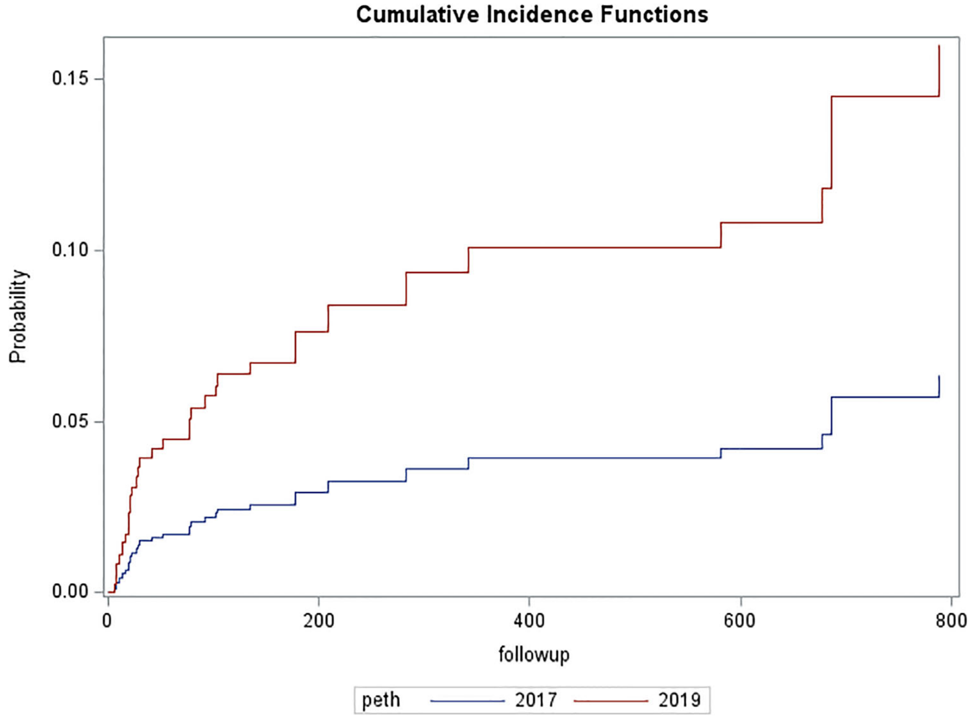

FIGURE 1 Cumulative incidence curves of the composite outcome of alcohol-related liver transplant evaluation terminations/ delistings due to alcohol use, stratified by PEth era

TABLE 3 Multivariable comparisons for composite outcome of alcohol-related evaluation terminations and delistings (as detected by testing)

	Comparison			Adjusted Hazard ratio (Confidence limits)	Pairwise comparison *P*-value	Variable *P*-value
Year	2019 (PEth)	versus	2017 (pre-PEth)	2.86 (1.67, 4.97)	<.001	<.001
BMI	<18.5	versus	18.5 < 25	*	*	<.001
	25–30			.37 (.17, .82)	.014	
	≥30			1.11 (.62, 1.99)	.736	

Patients were censored at transplant receipt. Death was considered as a competing risk only for patients placed on the transplant waiting list.
*Sample size too small for valid comparisons.

One limitation of our study is that we were unable to formally evaluate the effect of changing practices concerning abstinence for patients with alcohol-related indications for transplant. In recent years, many transplant centers have moved away from absolute guidelines for alcohol abstinence prior to consideration of candidates to a "case-by-case" basis, wherein select patients with alcohol-related hepatitis may be considered for transplantation. At the time of our analysis, our institution maintained a "zero tolerance" policy for detected alcohol use during the evaluation period and while wait-listed. We recognize that many health systems are moving towards providing more support and working with patients to meet program requirements for abstinence from alcohol. However, we do not believe this limits the generalizability of our main findings, since the ability to accurately detect alcohol use during the evaluation/ listing period can identify patients who could benefit from additional support in settings where patients with ongoing or relapsing alcohol use disorder may still be considered candidates for transplant. Another limitation of our analysis is that—due to the impact of the coronavirus pandemic—transplant operations within our health system effectively came to a halt for several months in 2020. As a result, we are unable to expand our study time frame to include more years of follow-up, which would allow us to identify a larger patient sample and perhaps include more variables in our analysis.

In conclusion, we found that a larger proportion of patients with alcohol-related liver disease had transplant evaluations terminated or were removed from waitlists due to alcohol use in 2019, after PEth testing was implemented, compared to 2017. The other significant factors associated with evaluation termination/ delisting included BMI; this is consistent with previous research and likely reflects overall health status. Larger studies encompassing a longer time frame are needed to clarify the impact of PEth testing on selection of candidates for liver transplant, and whether its use results in more successful long-term outcomes.

CONFLICT OF INTEREST

None to declare.

AUTHOR CONTRIBUTIONS

Concept/design: Ranya Selim, Sandra Naffouj, Omar AlShamaa, Abdelwahab Ahmed, Syed-Mohammed Jafri, Stuart C. Gordon, Humberto C. Gonzalez. Data analysis/interpretation: Ranya Selim, Yueren Zhou, Loralee B. Rupp, Sandra Naffouj, Omar AlShamaa, Abdelwahab Ahmed, Syed-Mohammed Jafri, Stuart C. Gordon, Antu Segal, Humberto C. Gonzalez Manuscript preparation: Ranya Selim, Loralee B. Rupp, Sheri Trudeau, Stuart C. Gordon, Antu Segal, Humberto C. Gonzalez

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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