Letter from the President

The Chronic Liver Disease Foundation (CLDF) continues in its mission of providing the best in-class educational activities in liver disease. As a not-for-profit educational organization that is led by an all-volunteer board of trustees, the CLDF has been able to continue its unique contributions in the field of viral hepatitis but also in other important areas of liver disease, such as non-alcoholic steatohepatitis (NASH), hepatic encephalopathy, hepatocellular carcinoma, and others. As of January 2020, we marked 18 years as an educational organization and foundation. As U.S. death rates from chronic liver disease continue to rise, we will continue to strive toward providing exceptional education and clinical solutions for the healthcare community.

In this context, 2019 was a record year for the CLDF, which would not have been possible without the generous support of our sponsors, faculty, and partnership organizations. In 2019, as an organization devoted to continuing medical education and clinical solutions, we reached over 4,100 clinicians and administered 211 programs, potentially affecting the lives of 223,000 patients.

That’s a testament to the commitment and professionalism of our expert clinical advisors, faculty, program staff, our CME accredited providers, and our network of collaborators. The success is also a result of significant investment in our processes, communication platforms, and innovation in our delivery of continuing education. We’ve asked more from our supporters than ever. But the result of all that effort is undeniable, as measured by speaker and attendee evaluations, and educational outcome assessments conducted by independent sources.

Our Foundation is thriving, and our future is vibrant. Each event, we work to empower healthcare providers who are at the forefront of battling chronic liver diseases with exceptional education, clinical research, and free health screenings.

As an exclusive not-for-profit foundation, the CLDF is proud to work with world-renowned experts who help develop and deliver our programs. The CLDF conducted advisory meetings in 2019 to gain guidance for our future educational programming with our expert partners during board and committee meetings. In the process, we have been able to develop a strong understanding of clinical practice gaps, educational needs, and educational objectives in 2020 and beyond. Clinical areas of CLDF in 2020 include improving knowledge, understanding, application and performance in the diagnosis, management and treatment of patients with complications of cirrhosis, hepatocellular carcinoma (HCC), non-alcoholic steatohepatitis (NASH), and viral hepatitis. Additionally, our outreach efforts will continue to expand to primary care, hospital providers, advance practice providers (APPs), and trainees. Our history of success, our forward-thinking approach, and our expert team members position us for a bright future.

Sincerely,

Zobair M. Younossi, MD
President, CLDF Board of Trustees
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2019 PROGRAMS
In 2019, the CLDF continued to join the global efforts in eliminating HCV by continuing the education and screening program: Triple E for HCV. This program focused on educating health care providers and patients in addiction/substance abuse facilities, as well as screening and linkage to care. The results of this initiative will be published as an abstract at EASL 2020.

- **Screening** for HCV
  - 2,713 persons screened
  - 1,131 (42%) Antibody +
  - 825 (73%) Blood Draw Completed
  - 552 (67%) HCV RNA +
  - 750 Educated

- **Educating** Patients & Staff

- **Counseling** Hepatitis Management Experts

TRIPLE E FOR HCV
TREATMENT EXPANSION IN HIGH-RISK COMMUNITIES
ENGAGEMENT, EDUCATION AND ERADICATION OF HCV
Partner Organizations in Global HCV Eradication
The CLDF and The New Mexico Peer Education Project (NMPEP), a collaboration between Project ECHO at the University of New Mexico Health Sciences Center and the New Mexico Corrections Department, leverages the ECHO Model to make a powerful and lasting intervention in prisoner and prison community health. NMPEP trains incarcerated individuals to increase their fellow prisoners’ knowledge about the most common health conditions impacting prison populations. The CLDF and NMPEP provided a comprehensive education program in hepatitis C with pronounced success reaching over 13,000 individuals.
HCC Innovations is a unique CME learning experience offering case-based education on the diagnosis, management, and treatment of HCC in a multi-disciplinary setting.

This initiative shadowed the ECHO model™ which dramatically increases access to specialty treatment in rural and underserved areas by providing front-line clinicians with the knowledge and support they need to manage patients with complex conditions.

Recordings of 22 customized topics in HCC are available on the CLDF website.

**Clinician Practice Impact**

Learner clinicians are 42% more likely to provide evidence-based care as compared to non-learners.

**Patient Reach**

*Due to this education, roughly 234 patients with HCC per week may benefit from improved evidence-based care.*
The CLDF has been provided HE clinical education for over a decade. This year the initiative was tailored to the specific needs of hospital-based health care professionals, in the format of grand round lectures.

**Clinician Practice Impact**
Following participation, clinicians are **39%** more likely to provide evidence-based care as compared to nonparticipants.

**Due to this education, over 6,390 patients with advanced liver disease per week may benefit from improved evidence-based care.**

- **579** number of attendees
- **86%** indicated that attending this activity will change their practice behavior
- **90%** indicated that attending this activity will increase their effectiveness in treating patients
NASH

Chronic Liver Disease Foundation
CLDF NASH Hepatology Leadership Forum convened experts in the field of NASH, clinical trials, advocacy, policy, therapeutics, and biomarker development to discuss current challenges and opportunities in the management of NASH. A working group was formed and tasked with creating straight-forward practical diagnosis and staging decision trees/algorithms for gastroenterologists, primary care and non-hepatology specialists that can be made readily available as a “living” web-based resource, for providers.

**Chairs**

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**CHRONIC LIVER DISEASE FOUNDATION WORKING GROUP RECOMMENDATIONS:**

**Practical Algorithms for NASH/LDINASH Screening for Primary Care, Non-Hepatology and Gastroenterology Practices**

Manal Abdelmalek, MD, MPH; Natarajan Ravendhran, MD; Zobair Younossi, MD, MPH; Leonard Seeff, MD; and Paul Kwo, MD

University of California, San Diego, CA; Northern Health, Vancouver, BC; Children’s Hospital, Columbus, OH

**Background:**

• NASH/LDINASH is a common cause of chronic liver disease in adults and children

• Most patients with NASH/LDINASH are asymptomatic

• A positive history of metabolic syndrome is the single best predictor of NASH/LDINASH

**Method:**

• A CLDF/NASH steering committee was held in October 2018

• A multi-center panel was formed and tasked with creating straight-forward practical diagnosis and staging decision trees/algorithms for gastroenterologists, primary care and non-hepatology specialists

**Conclusion:**

• The consensus diagnostic/therapeutic approach was endorsed for pediatric and adult populations

• Practical algorithms will be disseminated on the CLDF website for gastroenterologists, primary care, and non-hepatology specialists

• Algorithms are in progress, and will be used as educational tools in health-care providers
Understanding the global health concerns of NAFLD and NASH, the CLDF generated a phase IV trial that brought education to healthcare providers and patients, increased NASH trial recruitment and contributed to a national registry which will establish prospectively additional data on natural history, relationships of comorbidities, and house records for future research.

NASH Education AND Trial Awareness

Over 2000 patients screened with FibroScan®

18.5% identified for NASH trial assessment

Community outreach education on NASH diagnosis and screening reached over 3000 health care providers

NASH Trial Opportunity for Your Overweight Metabolic Syndrome Patients

A NASH trial is underway. Please view the video below to learn more about whether your patients might be eligible to participate.

Bradley Freilich MD, FAASLD, AGAF, CCI
Director
Kansas City Research Institute
Liver and Pancreas Institute
of Kansas City
Partner
Kansas City Gastroenterology and Hepatology

Click to play video
The goal of the Clinical Insights into the Management of Primary Biliary Cholangitis (PBC) was to provide important clinical data on issues related to the management of PBC to specialist and primary care clinicians, through live educational programming.

**Clinician Practice Impact**
Participant clinicians are 24% more likely to provide evidence-based care as compared to nonparticipants.

**Patient Reach**
The 406 healthcare providers who participated in this activity to date see, on average, 4 patients with PBC each month.

*Therefore, due to this education, roughly 1600 patients with PBC per month may benefit from improved evidence-based care.*
Sixty nominated 3rd year GI Fellows with an interest in hepatology convened for a two day meeting that included state-of-the-art lectures and break out sessions. The “young gun” forum delivered the opportunity to converse with CLDF expert mentors while providing important clinical practice management in hepatology.

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CLDF Website

www.chronicliverdisease.org
TRIPLE E FOR HCV: TREATMENT EXPANSION IN APPALACHIA ENGAGEMENT, EDUCATION AND ERADICATION OF HCV

MANAGEMENT CHALLENGES IN HCV

HEPATITIS DELTA VIRUS (HDV)

HCC INNOVATIONS (21 ECHO WEBCASTS)

HCC EPIDEMIOLOGY

CHEMOTHERAPY FOR HCC AND CHOLANGIOCARCINOMA

IMMUNOTHERAPY FOR HCC AND EMERGING TREATMENTS

OUTPATIENT CHALLENGES IN HE

NASH DISEASE STATE (8 WEBINARS)

UPDATES IN THE MANAGEMENT OF NASH

HEPATOLOGY NEWS TONIGHT MANAGING COMPLICATIONS OF CIRRHOSIS

COMPLICATIONS OF CIRRHOSIS: STRATEGIES TO IMPROVE LONG-TERM PATIENT OUTCOMES – PART 1

CLINICAL INSIGHTS INTO THE MANAGEMENT OF THE COMPLICATIONS OF CIRRHOSIS

CURRENT AND EMERGING MANAGEMENT APPROACHES FOR THE PATIENT WITH HEPATORENAL SYNDROME (HRS)

HOT TOPICS IN CIRRHOSIS: A CASE-BASED APPROACH TO ACUTE KIDNEY INJURY (AKI) AND HEPATORENAL SYNDROME (HRS)

MANAGING COMPLICATIONS OF CIRRHOSIS (HEPATORENAL SYNDROME & THROMBOCYTOPENIA)

PRIMARY BILIARY CHOLEANGITIS

HOT TOPICS IN CIRRHOSIS
CLDF 2019 Symposia

- **Triple E for HCV Satellite Symposium Series: Engagement, Education, and Eradication**
  - American Society of Addiction Medicine (ASAM)
  - National Conference on Corrections Healthcare (NCCHC)
  - American Association for the Treatment of Opioid Disorders (AATOD)

- **Hepatology News Tonight: Managing Complications of Cirrhosis** – Society of Hospital Medicine Conference

- **Hot Topics in Cirrhosis** – Digestive Disease Week

- **Hepatic Encephalopathy: The Pathway to Quality Care** – Case Management Society of America Conference

- **Hot Topics in Cirrhosis: A Case-Based Approach to Acute Kidney Injury (AKI) and Hepatorenal Syndrome (HRS)** – American Association for the Study of Liver Diseases
In addition to the live, online education and clinical solutions offered by our Foundation we strive to enhance in areas of research and publication. Review articles, research abstracts and educational outcomes assessments were published and presented in partnership with our faculty and outcome providers at EASL, DDW, ACG and AASLD in 2019.
Patients with substance use disorders (SUDs) are at extremely high risk for becoming infected with hepatitis C virus (HCV)

CLDF provided HCV education to recovery center staff and screening for >1,000 US patients at these centers

Staff education will allow for the sustainability of the model

45% (658/1475) of those tested were hepatitis C antibody positive

81% (531/658) underwent confirmatory HCV RNA testing

72% (384/531) were linked to care
Educational Overview
The goal of HE Pathway to Care was to provide important clinical data on issues related to the management of hepatic encephalopathy to specialist and primary care clinicians. Learning objectives were:

- Understand the complications and the consequences of chronic liver disease
- Describe the economic, patient and caregiver burdens associated with cirrhosis and HE
- Demonstrate the ability to properly treat HE patients and prevent recurrence of disease

Knowledge
Using pre/post onsite evaluations and ARS system data, key knowledge advancement was seen specifically in:

- Understanding the appropriate time to reevaluate a diagnosis of HE
- Determining the type of HE based on presenting symptoms
- Understanding the benefits of treatment with rifaximin
- Recogning the decline in cognitive function in patients with HE post-liver transplant

94% of participants believed that the educational learning objectives impacted their knowledge.

Competence
- 93% of participants indicated that this activity enhanced their professional effectiveness in treating patients
- 82% of participants indicated that this activity will result in a change in their practice behavior
- 21% of participants indicated that, as a result of participating in this activity, they will create or revise policies, and/or procedures
- 43% of participants indicated that, as a result of participating in this activity, they will change the management and treatment of their patients
- 55% of participants indicated that they have no barriers in implementing changes learned in this education

53% of participants believed that the educational learning objectives impacted their competence.

Conclusions
- High reach to nearly 700 clinicians through live interactive meetings.
- High satisfaction with content and faculty, nearly no perception of bias.
- Knowledge gains directly related to performance change, specifically in the understanding of the continued cognitive deficits after transplant and treatment.
- Strong overall performance effect, indicating likely lasting change.

Participation and Reach
Target Audience: 686 total clinicians who manage patients with advanced liver disease from 40 live local/regional meetings.

Participants see, on average, 14 patients each week with advanced liver disease (F3 or F4). Based on 686 participating clinicians, roughly 9,600 monthly touchpoints with patients with advanced liver disease may benefit from improved evidence-based care as a result of this program.

Satisfaction
Speaker was knowledgeable of subject matter: 99%

Material matched scope of practice: 92%

Speaker was effective in content delivery: 98%

Content was scientifically sound/free of bias: 99%

Speaker responded to questions: 99%

Provided handouts were useful: 92%

Performance
30-60 days after education participation, 42 participant clinicians were compared to 42 demographically similar nonparticipant clinicians with case-based surveys to assess performance. As a result of participating in this educational activity, participant clinicians are 35% (effect size 0.54) more likely than nonparticipants to manage a patient with advanced liver disease according to evidence, specifically in:

- Appropriate choice and titration of initial therapy
- Recognition of the continuation of cognitive deficits after HE treatment

36% of participants believed that the educational learning objectives would impact performance.

Continuing Educational Needs
Based on responses of participants and nonparticipants to the performance survey, the following topics are noted as continued needs for future educational activities:

- Awareness of the prevalence of cirrhosis in US patients
- Mechanism of action of lactulose
- Strategies to manage patient-related barriers to care, including adherence to therapy and access to supportive care
Expert Perspectives into the Management of PBC

EDUCATIONAL OVERVIEW
The goal of Expert Perspectives into the Management of Primary Biliary Cholangitis was to provide important clinical data on issues related to the management of PBC to specialist and primary care clinicians. Learning objectives were:
- Develop an evidence-based treatment regimen using the latest clinical evidence
- Explain the current and emerging treatment options for patients with PBC
- Recognize and communicate the risks and benefits of PBC therapy
- Identify barriers to the optimal management of patients with PBC

PARTICIPATION AND REACH
Target Audience: 616 total clinicians who manage patients with PBC from 57 live local/regional meetings.

Participants see, on average, 9 patients each year with PBC. Based on 616 participating clinicians, roughly 5,500 yearly touchpoints with patients with PBC may benefit from improved evidence-based care as a result of this program.

SATISFACTION
Speaker was knowledgeable of subject matter: 100%
Speaker was effective in content delivery: 99%
Speaker responded to questions: 100%
Material matched scope of practice: 100%
Content was scientifically sound/free of bias: 99%
Provided handouts were useful: 100%

CONTINUING EDUCATIONAL NEEDS
Based on responses of participants and nonparticipants to the performance survey, the following topics are noted as continued needs for future educational activities:
- Determining initial therapy and when to step up
- Managing appropriate dosing of OCA
- Appropriately managing pruritus in patients with PBC
- Increasing confidence in management
- Reinforce education with practical management, specifically for clinicians who do not have a large exposure to this patient population in their practices

CONCLUSIONS
- Knowledge improvements to practice change effects were seen, specifically regarding use of AMA for diagnosis, long-term monitoring, and understand how to treat with OCA.
- Comments from participants and nonparticipants indicated that PBC is often one of the more challenging therapeutic areas for these clinicians: there aren’t many activities available to them and they may not often see patients with PBC to practice skills.
- Continued education allowing case simulation may be needed to allow clinicians to practice newly acquired and reinforced skills even if their PBC patient load is not high.

KNOWLEDGE
Using pre/post onsite evaluations and ARS system data, key knowledge advancement was seen specifically in:
- Recognizing the relationship between gender and PBC
- Understanding the importance of AMA to diagnosis of PBC
- Understanding likelihood of adequate response after UDCA treatment
- Recognizing the mechanism of action, side effects, and likely outcome of OCA
- Appropriate long-term management of patients with PBC

93% of participants believed that the educational learning objectives impacted their knowledge.

COMPETENCE
94% of participants indicated that this activity enhanced their professional effectiveness in treating patients
85% of participants indicated that this activity will result in a change in their practice behavior
17% of participants indicated that, as a result of participating in this activity, they will create or revise policies, and/or procedures
47% of participants indicated that, as a result of participating in this activity, they will change the management and treatment of their patients

PERFORMANCE
30-60 days after education participation, 50 participant clinicians were compared to 50 demographically similar nonparticipant clinicians with case-based surveys to assess performance. As a result of participating in this educational activity, participant clinicians are more likely than nonparticipants to manage a patient with PBC according to evidence, specifically in:
- Using an AMA to confirm PBC diagnosis
- Recommending DEXA scans for long-term monitoring
- Adding OCA to the regimen of a patient with inadequate initial treatment response
- Appropriately managing fatigue in a patient with PBC
42% of participants believed that the educational learning objectives impacted their performance.
BACKGROUND

- Fibroscan is a clinically useful tool for non-invasive assessment of hepatic steatosis and fibrosis in patients with chronic liver disease (CLD).

AIM

- The aim was to assess its performance in a single center study.

METHODS

- Patients with various etiologies of chronic liver disease had Fibroscan administered during their routine visits.
- The diagnosis of advanced fibrosis was made in patients with liver stiffness of ≥11.4 kPa, advanced steatosis with controlled attenuation parameter (CAP) ≥260 kPa.
- Using laboratory data collected during the visits, we calculated non-invasive test (NT) scores for fibrosis:
  - FIB-4: advanced fibrosis in patients with the score ≥2.87;
  - AST-to-Platelet Ratio (APRI): advanced fibrosis with the score ≥1.0;
  - NAFLD Fibrosis Score (NFS): advanced fibrosis with the score ≥0.786.
- A subgroup of CLD patients had liver biopsy which, along with advanced fibrosis by NTIs, was used for assessment of concordance with Fibroscan (Table 1).
- Assessment was made in each major CLD etiology separately.
- Another subgroup of patients had Fibroscan administered twice (median period 12 months); those data was used to assess test-retest concordance of Fibroscan.

Table 1. Criteria for assessment of concordance.

<table>
<thead>
<tr>
<th>Cohen’s kappa statistic</th>
<th>Interpretation</th>
</tr>
</thead>
</table>
| K ≤ 0.01                | None to slight agreement
| 0.01 ≤ K ≤ 0.20         | None to slight agreement
| 0.21 ≤ K ≤ 0.40         | Fair agreement          |
| 0.41 ≤ K ≤ 0.60         | Moderate agreement      |
| 0.61 ≤ K ≤ 0.80         | Substantial agreement   |
| 0.81 ≤ K                | Almost perfect agreement|

CONCLUSIONS

- Non-invasive tests such as Fibroscan™, NFS, and FIB-4 provide useful information for assessment of advanced fibrosis in clinical practice of patients with chronic liver disease.

RESULTS

- There were 415 CLD patients enrolled in this single center study (including N=28 with chronic hepatitis B (CHB), N=32 with chronic hepatitis C (CHC), N=270 with non-alcoholic fatty liver disease (NAFLD) (Table 2).

Table 2. Clinical-demographic parameters of the study participants

<table>
<thead>
<tr>
<th>HBV</th>
<th>CHC</th>
<th>NAFLD</th>
<th>other</th>
<th>P</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>28</td>
<td>52</td>
<td>170</td>
<td>86</td>
<td>416</td>
</tr>
<tr>
<td>AGE</td>
<td>43.4±11.2</td>
<td>54.9±11.0</td>
<td>54.0±12.3</td>
<td>54.1±11.3</td>
<td>0.0002</td>
</tr>
<tr>
<td>Male gender</td>
<td>19 (67.9%)</td>
<td>19 (36.5%)</td>
<td>126 (73.5%)</td>
<td>32 (38.4%)</td>
<td>0.0043</td>
</tr>
<tr>
<td>White race</td>
<td>4 (14.3%)</td>
<td>21 (40.4%)</td>
<td>186 (102.5%)</td>
<td>54 (62.8%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Black race</td>
<td>3 (10.7%)</td>
<td>7 (13.5%)</td>
<td>72 (41.8%)</td>
<td>16 (18.8%)</td>
<td>0.0140</td>
</tr>
<tr>
<td>Hispanic</td>
<td>1 (3.6%)</td>
<td>1 (1.9%)</td>
<td>31 (18.3%)</td>
<td>10 (11.8%)</td>
<td>0.29</td>
</tr>
<tr>
<td>Asian race</td>
<td>33 (94.3%)</td>
<td>0 (0.0%)</td>
<td>21 (12.3%)</td>
<td>4 (4.7%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Type 2 diabetes</td>
<td>2 (7.1%)</td>
<td>6 (11.5%)</td>
<td>108 (63.0%)</td>
<td>17 (19.5%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>25.6±5.3</td>
<td>29.5±5.5</td>
<td>32.3±5.9</td>
<td>30.6±6.8</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>ALT, U/L</td>
<td>45.8±40.2</td>
<td>48.5±10.2</td>
<td>50.3±37.6</td>
<td>48.2±15.0</td>
<td>0.0094</td>
</tr>
<tr>
<td>AST, U/L</td>
<td>28.6±17.5</td>
<td>31.0±8.3</td>
<td>37.3±14.3</td>
<td>42.8±16.9</td>
<td>0.39</td>
</tr>
<tr>
<td>Platelet count, 10⁹/L</td>
<td>262.7±105</td>
<td>186.7±79</td>
<td>225.7±77</td>
<td>300.1±105</td>
<td>0.0016</td>
</tr>
<tr>
<td>Alkaline, g/L</td>
<td>4.1±1.0</td>
<td>3.9±1.0</td>
<td>4.1±3.6</td>
<td>3.8±1.8</td>
<td>0.0001</td>
</tr>
<tr>
<td>APRI</td>
<td>0.55±0.46</td>
<td>0.71±0.74</td>
<td>0.45±0.34</td>
<td>0.46±0.24</td>
<td>0.20</td>
</tr>
<tr>
<td>FIB-4</td>
<td>1.35±0.73</td>
<td>2.61±2.14</td>
<td>1.45±1.07</td>
<td>1.52±1.14</td>
<td>0.0007</td>
</tr>
<tr>
<td>NAFLD fibrosis score</td>
<td>2.68±1.73</td>
<td>3.07±1.31</td>
<td>2.70±1.64</td>
<td>3.18±1.51</td>
<td>0.0003</td>
</tr>
<tr>
<td>Fibrosis, pipes</td>
<td>5.8±3.65</td>
<td>12.3±3.33</td>
<td>8.4±3.19</td>
<td>7.0±4.06</td>
<td>0.0001</td>
</tr>
<tr>
<td>CAP, dB/m</td>
<td>25.7±4.4</td>
<td>242±5.7</td>
<td>308±5.1</td>
<td>234±6.4</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Advanced fibrosis by:
- Biopsy (Metavir ≥ 3) | 0.00% | 0 (0.0%) | 13 (5.0%) | 8 (9.9%) | 0.0006 | 43 (10.3%) |
- APRI (≥2.0) | 2 (28.6%) | 6 (12.5%) | 13 (6.7%) | 7 (7.9%) | 0.0130 | 28 (6.8%) |
- FIB-4 (≥2.67) | 0 (0.0%) | 0 (0.0%) | 14 (11.8%) | 7 (7.9%) | 0.0002 | 29 (6.8%) |
- NFS (≥0.676) | 0 (0.0%) | 0 (0.0%) | 14 (11.8%) | 7 (7.9%) | 0.0002 | 29 (6.8%) |
- Fibrosis (≥14.4 kPa) | 2 (2.1%) | 12 (23.5%) | 41 (32.5%) | 11 (13.2%) | 0.0050 | 86 (19.9%) |

Advanced steatosis by:
- Biopsy (≥ moderate) | 0 (0.0%) | 2 (4.0%) | 32 (29.4%) | 5 (5.9%) | 0.42 | 40 (9.6%) |

Fibroscan (≥ 200 pipes) | 55 (56.8%) | 13 (24.5%) | 233 (82.4%) | 42 (48.8%) | <0.0001 | 293 (69.4%) |

Patients were 53.4 ± 12.7 years old, 47% male, 56% white, 12% black, 10% Hispanic, 10% Asian, 33% with type 2 diabetes (Table 2).

- Patients with CHC had the highest mean liver stiffness (12.8±13.4 kPa vs. 7.9 ± 7.0 kPa in other CLD patients, p=0.0006) while patients with NAFLD had the highest CAP value (268±51 dB/m vs. 258±64 dB/m, p<0.0001) (Table 2).

- In patients with CHC, the highest concordance of advanced fibrosis by FS was by FIB-4 score (K = 0.59 (0.25-0.91)) and APRI (K = 0.46 (0.12-0.81)) (Table 3).

- Similarly, in patients with NAFLD, the highest concordance of advanced fibrosis by FS was with the stage of histologic fibrosis by liver biopsy (K = 0.55 (0.35-0.74)) and NFS score (K = 0.50 (0.32-0.67)) (Table 3).

- The test-retest concordance for advanced fibrosis by Fibroscan was substantial (K = 0.70 (0.41-0.97)) and moderate for advanced steatosis (K = 0.41 (0.12-0.79), agreement in 38/49 patients).

Table 3. Concordance of NTIs, Fibroscan, and liver biopsy in patients with different CLD etiologies.

<table>
<thead>
<tr>
<th>Method used for advanced fibrosis</th>
<th>CHC</th>
<th>NAFLD</th>
</tr>
</thead>
<tbody>
<tr>
<td>APRI (≥2.0)</td>
<td>0.46 (0.12-0.81)</td>
<td>0.25 (0.08-0.42)</td>
</tr>
<tr>
<td>FIB-4 (≥2.67)</td>
<td>0.58 (0.25-0.91)</td>
<td>0.36 (0.19-0.54)</td>
</tr>
<tr>
<td>NFS (≥0.676)</td>
<td>0.25 (0.09-0.59)</td>
<td>0.59 (0.32-0.67)</td>
</tr>
<tr>
<td>Biopsy (≥ moderate)</td>
<td>not available (insufficient sample size)</td>
<td>0.55 (0.35-0.74)</td>
</tr>
<tr>
<td>Biopsy (≥ moderate)</td>
<td>not available (insufficient sample size)</td>
<td>-0.07 (-0.29-0.14)</td>
</tr>
</tbody>
</table>
Diagnosis and Management of Primary Biliary Cholangitis: American Journal of Gastroenterology: Supplement January 2019

INTRODUCTION

Primary biliary cholangitis (PBC) is a chronic, cholestatic, autoimmune disease with a variable progressive course. PBC can cause debilitating symptoms including fatigue and pruritus and, if left untreated, is associated with a high risk of cirrhosis and related complications, liver failure, and death. Recent changes to the PBC landscape include a name change, updated guidelines for diagnosis and treatment as well as new treatment options that have recently become available. Practitioners face many unmet questions when managing PBC. To assist these healthcare providers in managing patients with PBC, the American College of Gastroenterology (ACG) Institute for Clinical Research & Education, in collaboration with the Chronic Liver Disease Foundation (CLDF), reported a panel of experts to evaluate and summarize the most current and relevant peer-reviewed literature regarding PBC. This, combined with the extensive experience and clinical expertise of this expert panel, led to the formation of this clinical guidance on the diagnosis and management of PBC.

Primary biliary cholangitis (PBC) is a chronic, cholestatic autoimmune liver disease that affects bile ducts. It is characterized by progressive destruction of intrahepatobiliary bile ducts and is associated with elevated serum levels of alkaline phosphatase (ALP). Although different laboratories have different upper limits of normal for ALP, serum ALP levels typically exceed age-related normal levels in people with a family member, especially an identical twin, with extrahepatic autoimmune diseases or a higher prevalence of PBC between 2004 and 2014. Although women are predominantly affected, some men are also affected.

DIAGNOSIS OF PBC

Without identification and subsequent intervention, a substantial number of PBC patients progress to liver failure, transplantation, or death within 10 years [5]. In fact, one study, only 74% of patients remained free from liver failure 10 years after the diagnosis of PBC [5]. Regardless of ethnicity, the immunological response triggered in PBC is directed against biliary epithelial cells. Anti-entirethelial antibodies (AEAs), which are highly disease specific, are directed against the 3.4-kDa and 3-kDa autoantigens of the inner mitochondrial membrane, of which the main target is the E2 subunit of the Pyruvate Dehydrogenase Complex (PDC-E2). Expression of PDC-E2 is a multifaceted 3.4-kDa protein that stows with certain autoantibody-PC-2 antibodies is increased on bile epithelial cells of patients with PBC. In addition, overexpressed mitogen-activated protein kinase (MAPK) targets for the integration of biliary antigens into PDC-E2 have undergone similar epitopes to those of PC-2. Increased PDC-E2 mRNA may result in a loss of functional tolerance and an increase of autoimmune cholate differentiation (E2m1-PC-2-specific T cells in the liver) [6]. The autoimmune T-cell response that follows is characterized by damage to the bile epithelial cells that leads to the intraductal bile ducts, periductal fibrosis, and eventual ductular lobe and portal fibrotic scars. This leads to bile leakage through bile ducts into the perivenous spaces. Histopathies are studied by Dr. Morris and colleagues, leading to biopsy, and cirrhosis [7, 8, 9, 10] (Fig. 1).

HISTORICAL OVERVIEW

PBC is commonly characterized by a disease progression of cholestasis followed by hepatic and extrahepatic complications and in some cases, death. The epidemiology of PBC has been described in a number of studies. The Vanderbilt University (VU) cohort included patients with biopsy-proven PBC. The median age at diagnosis was 52 years, and patients were mostly women. Female gender has been described as an independent risk factor for the development of PBC [11]. Although PBC typically develops in middle-aged adult females, it can present at a young age or at any age. Age at diagnosis in women was 50 years (range, 16–80 years), and in men was 55 years (range, 30–80 years).

The rate of new cases of PBC varies amongst patients, some do progress through these phases, while others may remain stable for years. The rate of new cases of PBC within a population. Data from the Rochester Epidemiology Project support this conclusion. Patients at diagnosis of PBC are predominantly reported in white females aged 40 to 50 years of age. Most patients are diagnosed at a young age while others remain asymptomatic for decades.

The prevalence of PBC is considered a relatively rare disease that has historically been predominantly reported in white females aged 40 to 50 years of age. Most patients are diagnosed at a young age while others remain asymptomatic for decades. The prevalence of PBC between 2004 and 2014 was 4.5 (95% confidence interval [CI], 3.1–6.0) cases per 100,000 person-years. The rate of new cases of PBC varies amongst patients, some do progress through these phases, while others may remain stable for years. The rate of new cases of PBC within a population. Data from the Rochester Epidemiology Project support this conclusion. Patients are predominantly reported in white females aged 40 to 50 years of age. Most patients are diagnosed at a young age while others remain asymptomatic for decades.

Clinical features of PBC include fatigue, pruritus, concurrent autoimmune disease(s), autoimmune triad, primary biliary fibrosis, and extrahepatic cholangitis [1]. In addition, the diagnosis of PBC is made by the combination of a positive AMA test and a liver biopsy with typical histologic changes. However, the prevalence of PBC between 2004 and 2014 was 4.5 (95% confidence interval [CI], 3.1–6.0) cases per 100,000 person-years. The rate of new cases of PBC varies amongst patients, some do progress through these phases, while others may remain stable for years. The rate of new cases of PBC within a population. Data from the Rochester Epidemiology Project support this conclusion. Patients are predominantly reported in white females aged 40 to 50 years of age. Most patients are diagnosed at a young age while others remain asymptomatic for decades.

Increased immunoglobulin concentrations, particularly immuno- globulin M (IgM), can be observed in patients with PBC. In contrast, increased immunoglobulin G (IgG) is seen in ASH while decreased serum immunoglobulin M (IgM) can be observed in patients with alcoholic liver disease [5]. As PBC progresses, hepatocellular dysfunction may occur. Elevated serum bilirubin and alanine aminotransferase levels may be detected by imaging. Regardless, abdominal ultrasound should be performed to exclude mechanical bile duct obstruction or any other cause of liver dysfunction associated with progressive liver disease. During hepatocellular dysfunction, bilirubinuria and decreased biliary excretion of copper may occur. Serum copper levels are significantly and negatively correlated with disease activity.

SAFETY thermal tolerance during physical exercise, and subsequent liver cirrhosis. A physical examination should include screening for hepatosplenomegaly and splenomegaly as well as serological signs of advanced liver disease. Liver examination should be performed to exclude mechanical bile duct obstruction or any other cause of liver dysfunction associated with progressive liver disease. The diagnosis of primary biliary cirrhosis (PBC) in the absence of other liver diseases and serious disease [16]. It is important to note that liver biopsy is not required for PBC. In cases where patients do not have abnormal liver function tests and serum autoantibodies (AMA), appropriate diagnostic testing should be performed to exclude other liver diseases or autoimmune diseases.

The prevalence of PBC in women was 4.5 (95% confidence interval [CI], 3.1–6.0) cases per 100,000 person-years. The rate of new cases of PBC varies amongst patients, some do progress through these phases, while others may remain stable for years. The rate of new cases of PBC within a population. Data from the Rochester Epidemiology Project support this conclusion. Patients are predominantly reported in white females aged 40 to 50 years of age. Most patients are diagnosed at a young age while others remain asymptomatic for decades.

In contrast, elevated serum bilirubin and alanine aminotransferase levels may be detected by imaging. Regardless, abdominal ultrasound should be performed to exclude mechanical bile duct obstruction or any other cause of liver dysfunction associated with progressive liver disease. During hepatocellular dysfunction, bilirubinuria and decreased biliary excretion of copper may occur. Serum copper levels are significantly and negatively correlated with disease activity.

SAFETY thermal tolerance during physical exercise, and subsequent liver cirrhosis. A physical examination should include screening for hepatosplenomegaly and splenomegaly as well as serological signs of advanced liver disease. Liver examination should be performed to exclude mechanical bile duct obstruction or any other cause of liver dysfunction associated with progressive liver disease. During hepatocellular dysfunction, bilirubinuria and decreased biliary excretion of copper may occur. Serum copper levels are significantly and negatively correlated with disease activity.
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