UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM

UNIVERSITY OF MIAMI
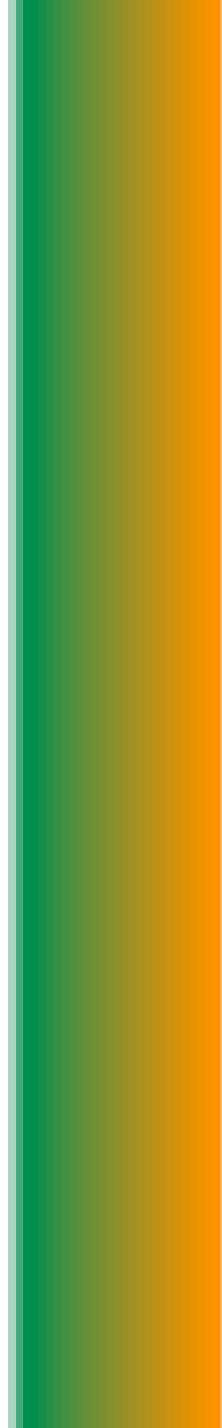## MILLER SCHOOL of MEDICINE

Nonalcoholic Steatohepatitis:
Identification and Evolving Treatment Strategies

**Final Outcome Report
for NASH in Two Cities**

Emerging
Challenges
In Primary Care: 2015

Report Date: January 8, 2016

Prepared By: **NACE**

Course Director

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Activity Planning Committee

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Course Accreditation

The University of Miami Leonard M. Miller School of Medicine is accredited by the Accreditation Council (ACCME) for Continuing Medical Education to provide continuing medical education for physicians.

The University of Miami Leonard M. Miller School of Medicine designates this live activity for a maximum of *1.25 AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Commercial Support

Cities and Dates

Emerging Challenges in Primary Care: Update 2015
Conference Schedule

May 2, 2015
Miami, FL

May 9, 2015
Baltimore, MD

*May 16, 2015
Tampa, FL

May 30, 2015
Atlanta, GA

June 6, 2015
Birmingham, AL

*June 13, 2015
Raleigh, NC

June 20 ,2015
Columbus, OH

*June 27, 2015
Troy, MI

August 15, 2015
Denver, CO

August 22, 2015
St. Louis, MO

*August 29, 2015
Houston, TX

September 12, 2015
Anaheim, CA

September 19, 2015
Sacramento, CA

September 26, 2015
Ft. Lauderdale, FL

October 3, 2015
San Antonio, TX

October 10, 2015
Uniondale, NY

***October 17, 2015
San Diego, CA**

**October 24, 2015
Nashville, TN**

*Simulcast and Live Conference

*Bolded cities where lecture was given

Titles of Presentations

Preventing Stroke in Patients with Atrial Fibrillation: New Concepts and Controversies Control
Elizabeth A. Jackson MD, MPH

A Primary Care Approach to Prostate Cancer - The Role of Shared Decision Making in Screening
Matt T. Rosenberg, MD

Translating the Advances in Evidence Based Medicine into Better Health Outcomes for People with Heart Failure
Ola Akinboboye, MD, MPH, MBA, FACP, FACC, FASNC, FSCCT, FAHA, DABSM; Jan Basile, MD; Phillip B. Duncan, MD; Icilma V. Fergus, MD, FACC; Elizabeth Ofili, MD, MPH, FACC; Anekwe Onwuanyi, MD; Laurence O. Watkins, MD, MPH, FACC; or Karol E. Watson, MD, PhD

Lipid Management and Cardiovascular Risk Reduction: The Evolving Treatment Paradigm
Ola Akinboboye, MD, MPH, MBA, FACP, FACC, FASNC, FSCCT, FAHA, DABSM; Jan Basile, MD; Phillip B. Duncan, MD; Icilma V. Fergus, MD, FACC; Elizabeth Ofili, MD, MPH, FACC; Anekwe Onwuanyi, MD; Laurence O. Watkins, MD, MPH, FACC; or Karol E. Watson, MD, PhD

Nonalcoholic Steatohepatitis: Identification and Evolving Treatment Strategies
Kalyan R. Bhamidimarri, MD, MPH

Chronic Hepatitis C: Update on Screening, Diagnosis, Management, and Promising New Treatments
Kalyan R. Bhamidimarri, MD, MPH

Levels of Evaluation

Consistent with the policies of the ACCME, NACE evaluates the effectiveness of all CME activities using a systematic process based on Moore's model. This outcome study reaches Level 5.

- Level 1: Participation

- Level 2: Satisfaction

- Level 3: Declarative and Procedural Knowledge

- Level 4: Competence

- Level 5: Performance

- Level 6: Patient Health

- Level 7: Community Health

Moore DE Jr, Green JS, Gallis HA. Achieving desired results and improved outcomes: integrating planning and assessment throughout learning activities.J Contin Educ Health Prof. 2009 Winter;29(1):1-15

Level 1: Participation

- 551 attendees in 2 cities
- 45% Physicians; 51% NPs or PAs; 2% RNs; 2% Other
- 55% in community-based practice
- 71% PCPs, 3% Cardiologist; 2% Endocrinologist; 24% Other or did not respond
- 93% provide direct patient care

Did we reach the right audience?   Yes!

Level 2: Satisfaction

- 99% rated the activity as excellent
- 99% indicated the activity improved their knowledge
- 95% stated that they learned new and useful strategies for patient care
- 90% said they would implement new strategies that they learned in their practice
- 100% said the program was fair-balanced and unbiased

Sample Size: N = approximately 551

Were our learners satisfied? Yes! Data were collected across two cities for the Emerging Challenges in Primary Care program.

Nonalcoholic Steatohepatitis:
Identification and Evolving Treatment Strategies

Patients seen each week in a clinical setting with Nonalcoholic Steatohepatitis:
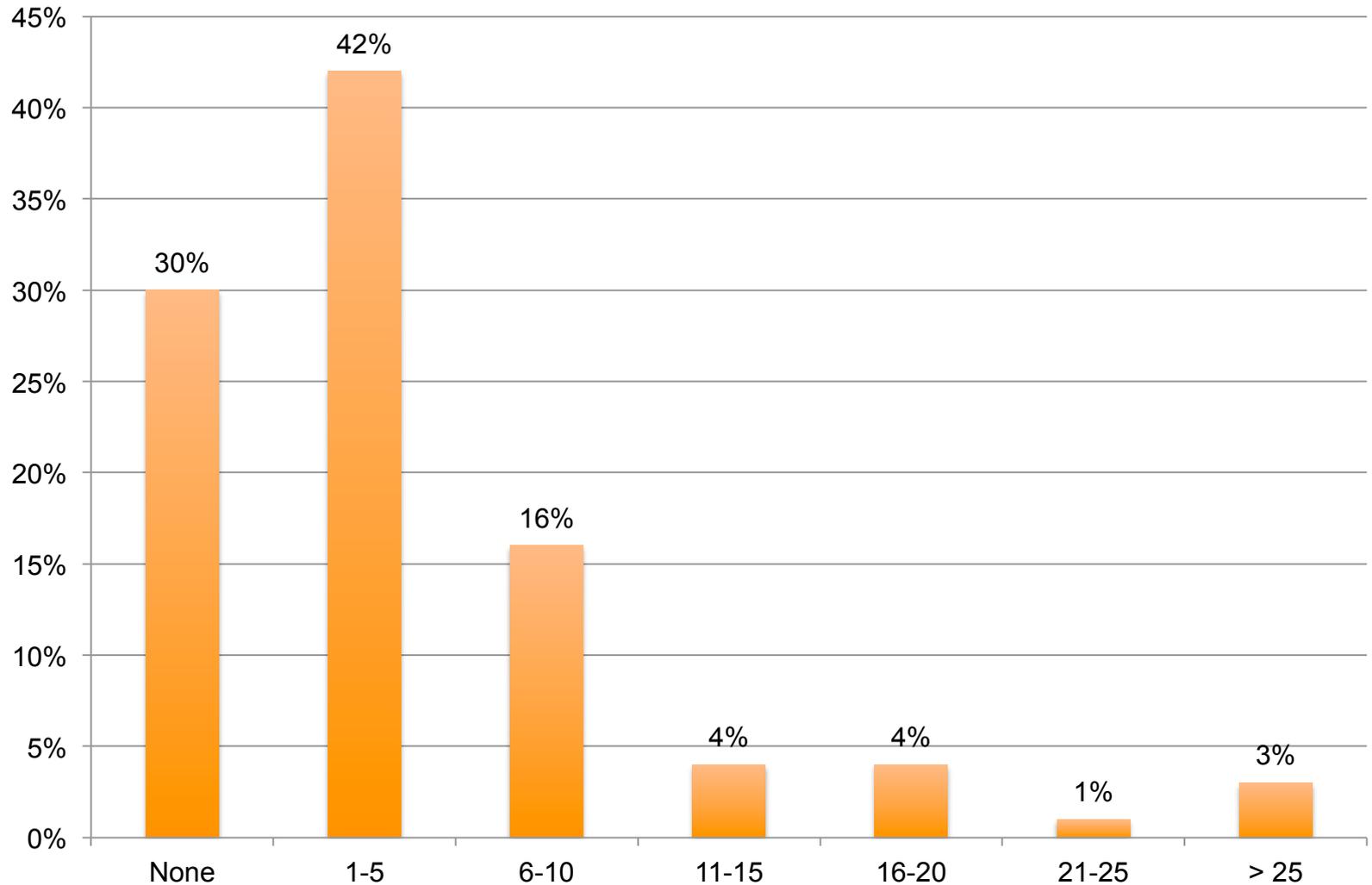
Sample Size: N = approximately 551

Did Learners Say They Achieved Learning Objective?

Upon completion of this activity, I can now – Identify patients at high risk for nonalcoholic fatty liver disease (NAFLD); distinguish non-alcoholic fatty liver (NAFL) from nonalcoholic steatohepatitis (NASH) and understand how to stage the disease; implement ongoing evidence based general management of patients with NASH; and describe the available and emerging treatment options for patients with NASH.

Category	Percentage
Yes	76%
Somewhat	21%
Not at all	3%
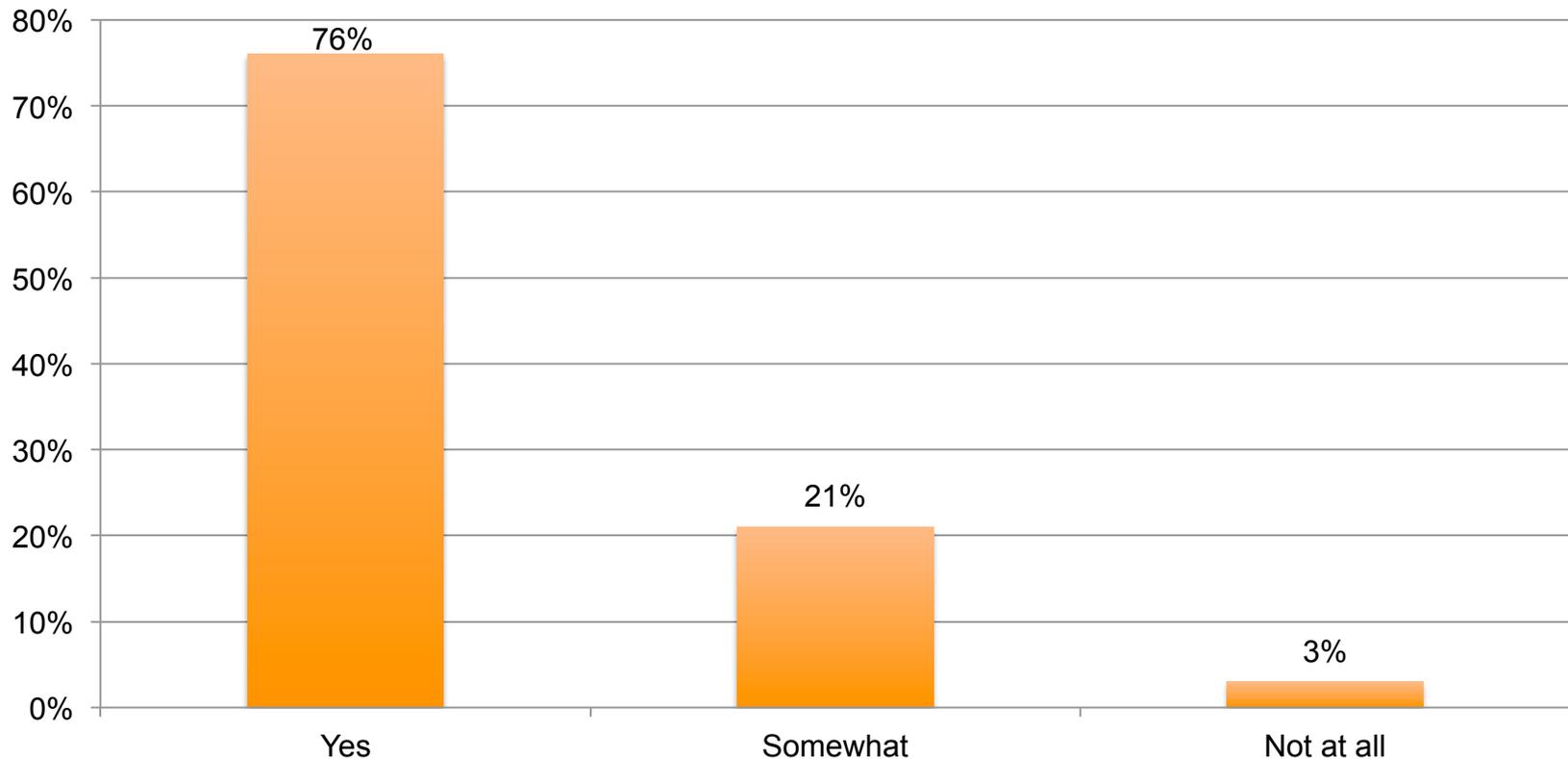
Yes! 97% believed they did. Data was collected in 2 cities.

Sample Size: N = approximately 551

Outcome Study Methodology

Goal

To determine the effect this CME activity had on learners with respect to competence to apply critical knowledge, confidence in treating patients with diseases or conditions discussed, and change in practice behavior.

Dependent Variables

1. **Level 3-5: Knowledge, Competence, and Performance**

   Case-based vignettes and pre- and post-test knowledge questions were asked with each session in the CME activity. Identical questions were also asked to a sample of attendees 4 weeks after the program to assess retention of knowledge. Responses can demonstrate learning and competence in applying critical knowledge. The use of case vignettes for this purpose has considerable predictive value. Vignettes, or written case simulations, have been widely used as indicators of actual practice behavior. [1]

2. **Practitioner Confidence**

   Confidence with the information relates directly to the likeliness of actively using knowledge. Practitioner confidence in his/her ability to diagnose and treat a disease or condition can affect practice behavior patterns.

3. **Level 5: Self-Reported Change in Practice Behavior**

   Four weeks after CME activity, practitioners are asked if they changed practice behavior.

1. Peabody, J.W., J. Luck, P. Glassman, S. Jain, J. Hansen, M. Spell and M. Lee (2004). Measuring the quality of physician practice by using clinical vignettes: a prospective validation study. Ann Intern Med14(10): 771-80.

Outcome Study Methodology (Cont.)

4. **Readiness to Change Behavior (Prochaska and DeClemente Model)**
   CME activities can motivate providers to move through different stages of change which can ultimately lead them to take action and modify their practice behavior in accordance with the objectives of the education.   Movement through these stages of change is an important dependent variable to consider in evaluating the impact of CME. Participants were asked to evaluate their stage of change with respect to specific topics being presented.

   – **Pre-contemplation stage**: I do not manage (XXX illness), nor do I plan to this year.
   – **Contemplation stage:** I did not manage (XXX illness) before this course, but as a result of attending this course I'm thinking of managing it now.
   – **Pre-contemplation/confirmation stage**: I do manage patients with (XXX Illness) and this course confirmed that I do **not** need to change my treatment methods.
   – **Preparation for action stage**: I do manage patients with (XXX illness) and this course helped me change my treatment methods.

Prochaska, et al (1988). Journal of Consulting and Clinical Psyhcology., 56, 520-528.

Nonalcoholic Steatohepatitis:
Identification and Evolving Treatment Strategies

Faculty
Kalyan R. Bhamidimarri, MD, MPH

Learning Objectives

1. Identify patients at high risk for nonalcoholic fatty liver disease (NAFLD).

2. Distinguish non-alcoholic fatty liver (NAFL) from nonalcoholic steatohepatitis (NASH) and understand how to stage the disease.

3. Implement ongoing evidence based general management of patients with NASH.

4. Describe the available and emerging treatment options for patients with NASH.

Key Findings

Nonalcoholic Steatohepatitis:
Identification and Evolving Treatment Strategies

Knowledge/Competence	Learners demonstrated significant improvement from pre to post-testing in their answers to *four* out of *four* of the case-based questions regarding treating a patient with Nonalcoholic Steatohepatitis.
Confidence	Whereas the majority of learners rated themselves as having very low confidence in their treating patients with Nonalcoholic Steatohepatitis before the education, most of the learners showed moderate gains in confidence after the program.
Intent to Perform	As a result of this program, 31% of learners who did not treat patients with Nonalcoholic Steatohepatitis before this course, but as a result of attending this course are considering doing so, while 49% indicated that they will change their treatment methods.
Change of Practice Behavior N= 50	86% of learners who responded to our four week survey indicated that they had changed their practice behavior to implement the learning objectives of this program within four weeks after they attended the activity.

Case Vignette Knowledge and Competence Assessment Questions
(presented before and after lecture—boxed answer is correct)

Which of the following patients are not at high risk for the development of NAFLD:
(Learning Objective 1)

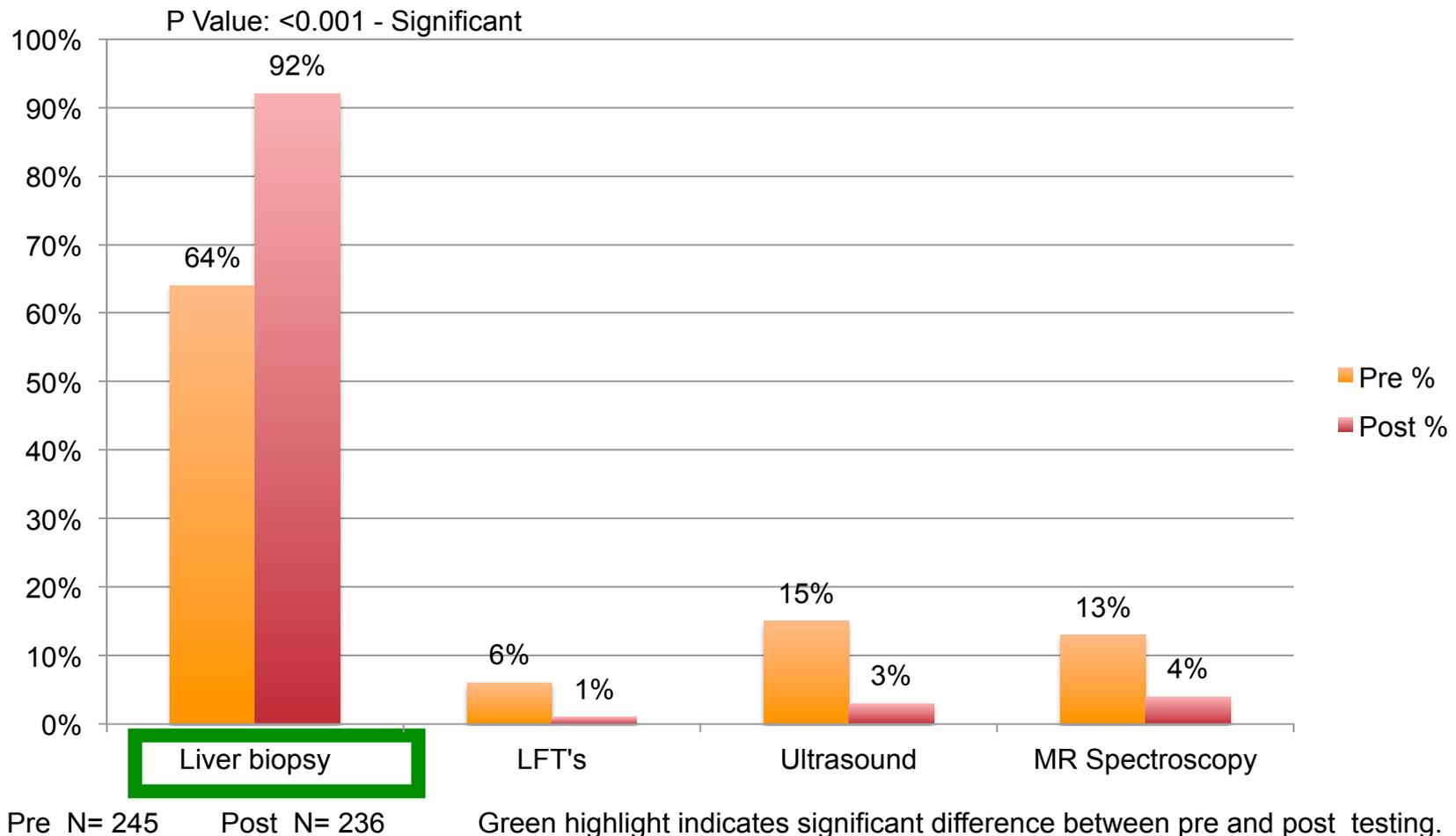P Value: 0.017 - Significant
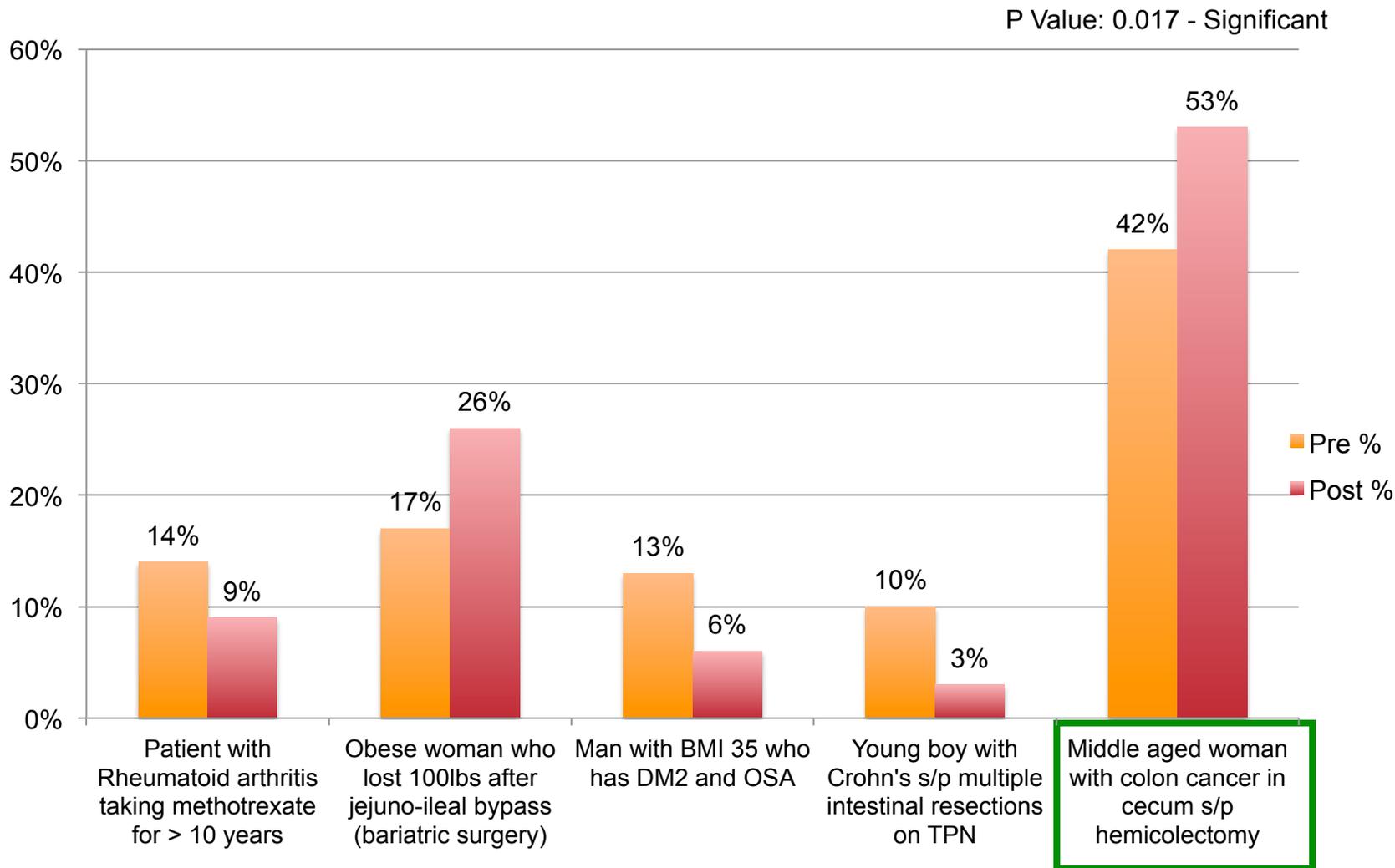
Pre N= 241   Post N= 231

Green highlight indicates significant difference between pre and post testing.

Case Vignette Knowledge and Competence Assessment Questions
(presented before and after lecture—boxed answer is correct)

62 year old Caucasian man with Obesity (BMI 45), DM2, Hypertension, Hyperlipidemia, Obstructive Sleep Apnea, and Osteoarthritis of the knees has mildly elevated LFT's in the past which were attributed to him being on statins. Despite all efforts to lose weight, the patient was able to lose only 2% of his weight due to his limited exercise capacity. Ultrasound demonstrates increased echogenicity of the liver suggestive of fatty liver.

What is the current gold standard to distinguish NAFLD from NASH:
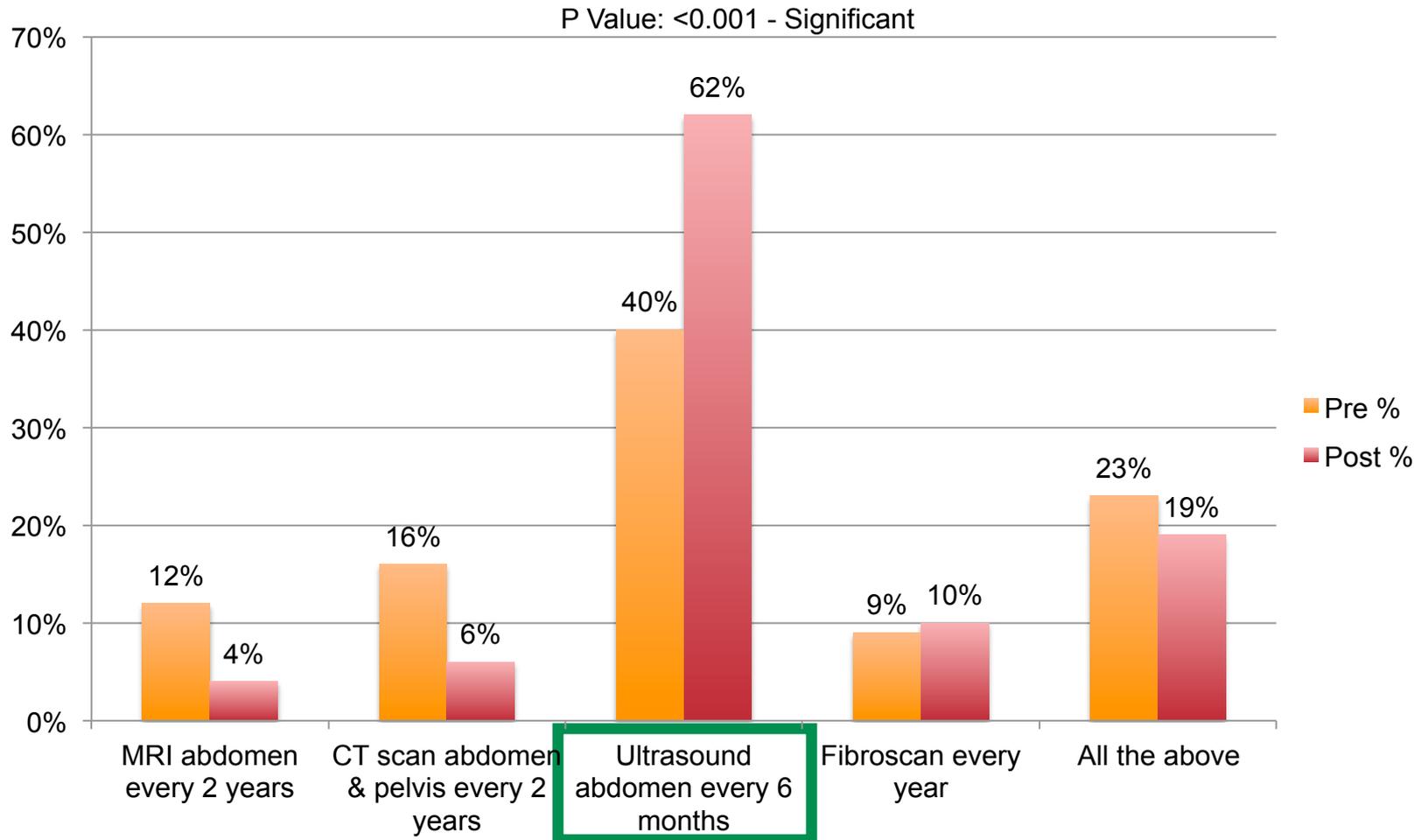(Learning Objective 2)

P Value: <0.001 - Significant

Pre N= 245   Post N= 236   Green highlight indicates significant difference between pre and post testing.

Case Vignette Knowledge and Competence Assessment Questions
(presented before and after lecture—boxed answer is correct)

68 year old Hispanic woman with Metabolic syndrome has new onset ascites and was hospitalized recently for fluid overload. Blood tests show serum albumin of 2.4, platelets of 98k and upper endoscopy which showed grade 2 varices. She underwent a transjugular liver biopsy which shows stage 4 fibrosis.

Given the clinical picture which is consistent with decompensated cirrhosis, how would you screen the patient for hepatocellular carcinoma?   (Learning Objective 3)

P Value: <0.001 - Significant
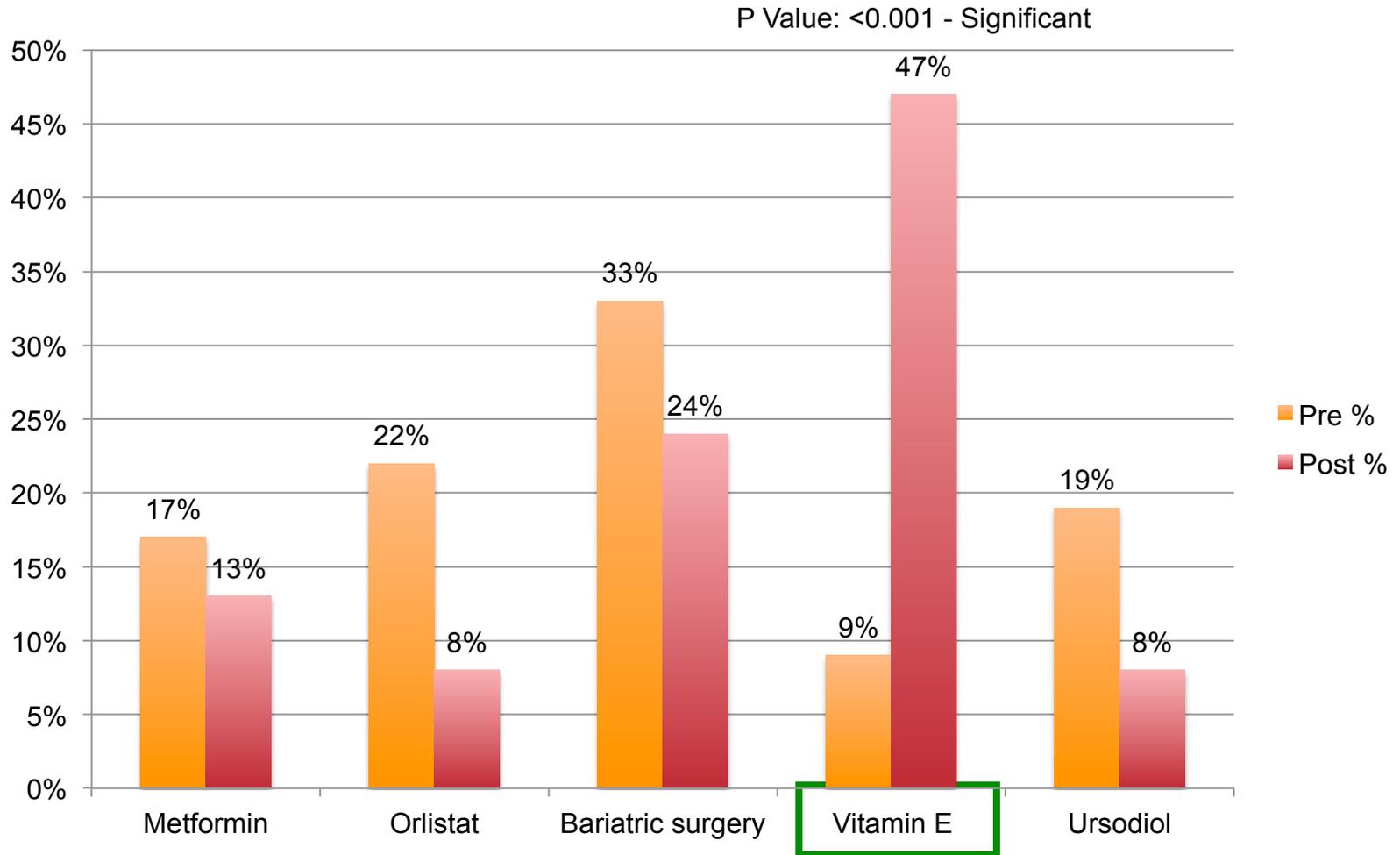
Pre N=230   Post N= 253   Green highlight indicates significant difference between pre and post testing.

Case Vignette Knowledge and Competence Assessment Questions
(presented before and after lecture—boxed answer is correct)

55 year old non-diabetic woman is recently diagnosed with NASH and advanced fibrosis (stage 3) on liver biopsy. You recommend aggressive life-style modifications but the patient was unable to lose > 1% of her body weight over a period of 1 year.

Given the presence of advanced fibrosis in the setting of NASH, which of the following additionally would you recommend in her management that would improve her liver histology? (Learning Objective 4)
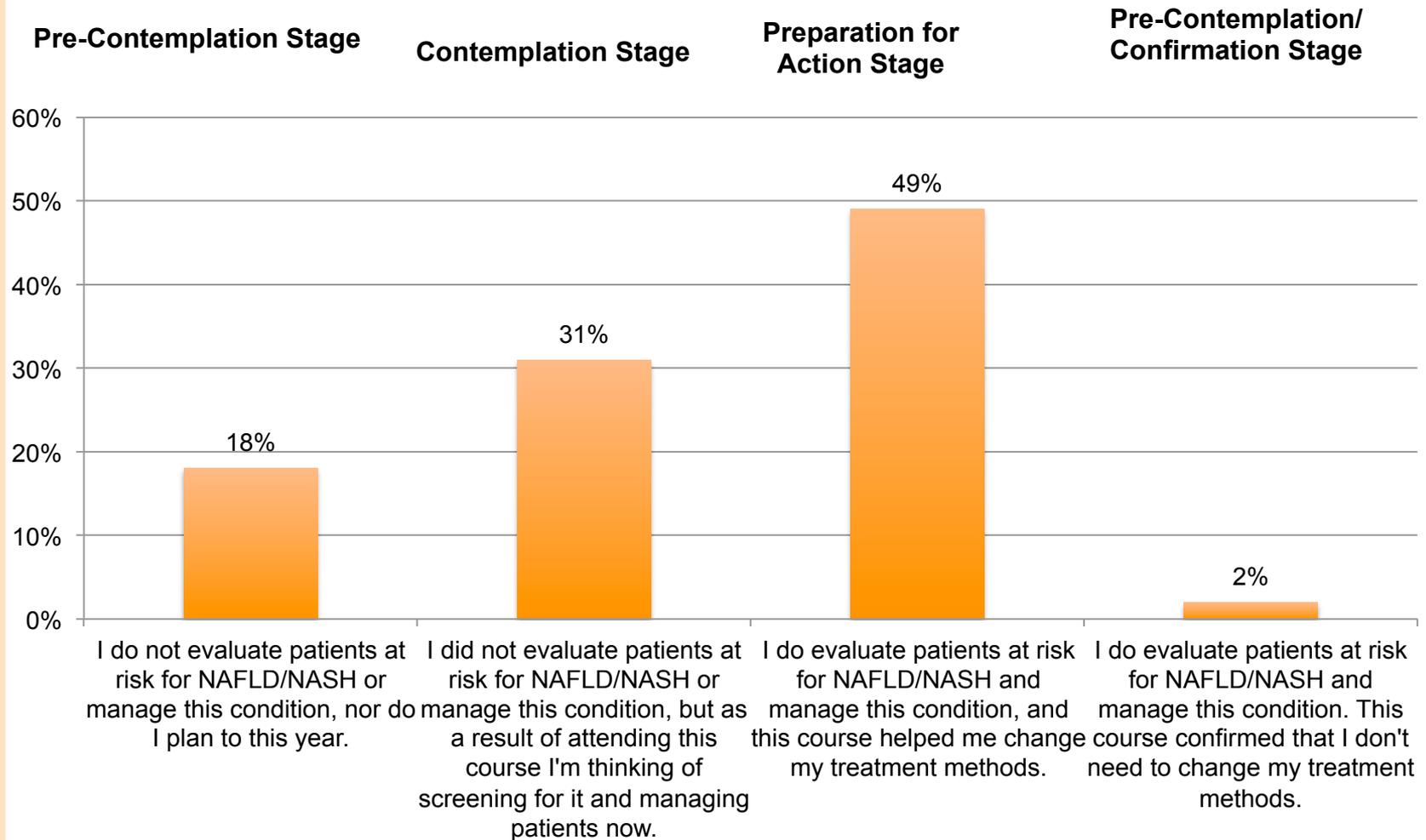
P Value: <0.001 - Significant

Pre N= 218   Post N= 242

Green highlight indicates significant difference between pre and post testing.

Change in Practice Behavior Question
(presented after the lecture)

Which of the statements below describes your approach to the evaluation and management of Non-Alcoholic Fatty Liver Disease and Non-Alchoholic Steatohepatitis?
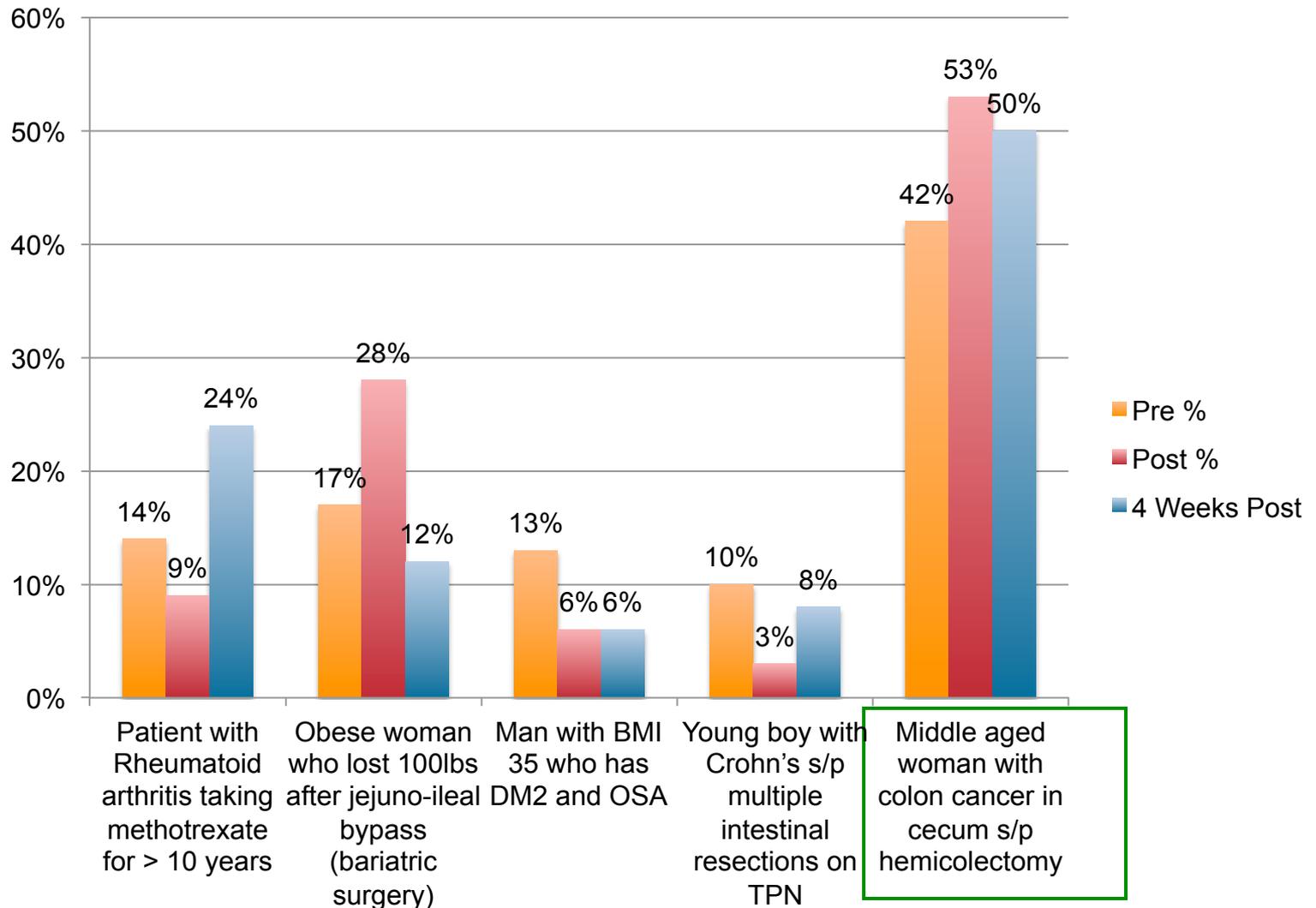

N= 155

Four Week Case Study Questions
(boxed answer is correct)

Which of the following patients are not at high risk for the development of NAFLD: (Learning Objective 1)

Legend:
- Pre %
- Post %
- 4 Weeks Post

Data by category:

Category	Pre %	Post %	4 Weeks Post
Patient with Rheumatoid arthritis taking methotrexate for > 10 years	14%	9%	24%
Obese woman who lost 100lbs after jejuno-ileal bypass (bariatric surgery)	17%	28%	12%
Man with BMI 35 who has DM2 and OSA	13%	6%	6%
Young boy with Crohn's s/p multiple intestinal resections on TPN	10%	3%	8%
Middle aged woman with colon cancer in cecum s/p hemicolectomy	42%	53%	50%

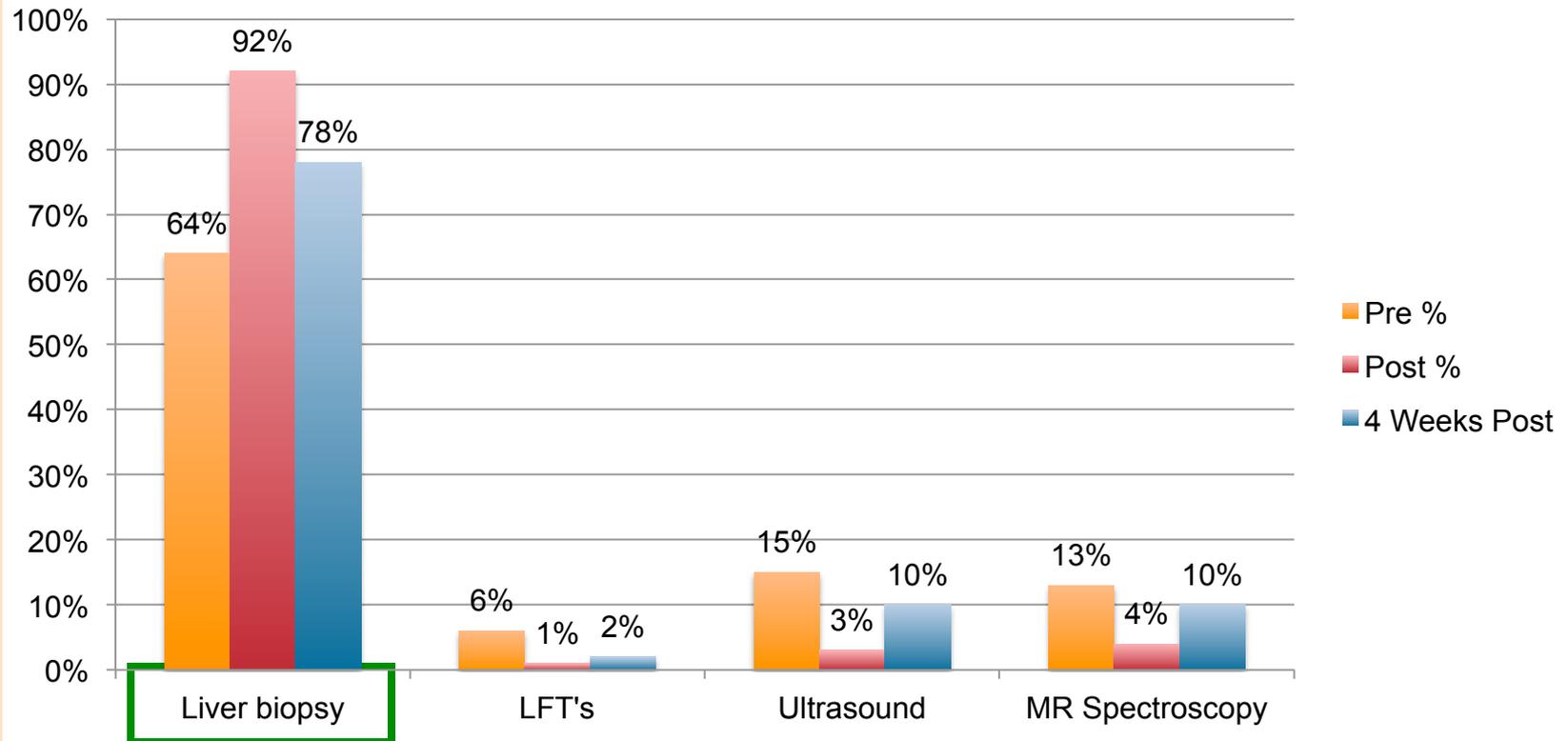Pre N= 241 Post N= 231
4 Week Post N = 50

Green highlight indicates significant difference between pre and post testing.

Four Week Case Study Questions
(boxed answer is correct)

62 year old Caucasian man with Obesity (BMI 45), DM2, Hypertension, Hyperlipidemia, Obstructive Sleep Apnea, and Osteoarthritis of the knees has mildly elevated LFT's in the past which were attributed to him being on statins. Despite all efforts to lose weight, the patient was able to lose only 2% of his weight due to his limited exercise capacity. Ultrasound demonstrates increased echogenicity of the liver suggestive of fatty liver.

What is the current gold standard to distinguish NAFLD from NASH:
(Learning Objective 2)

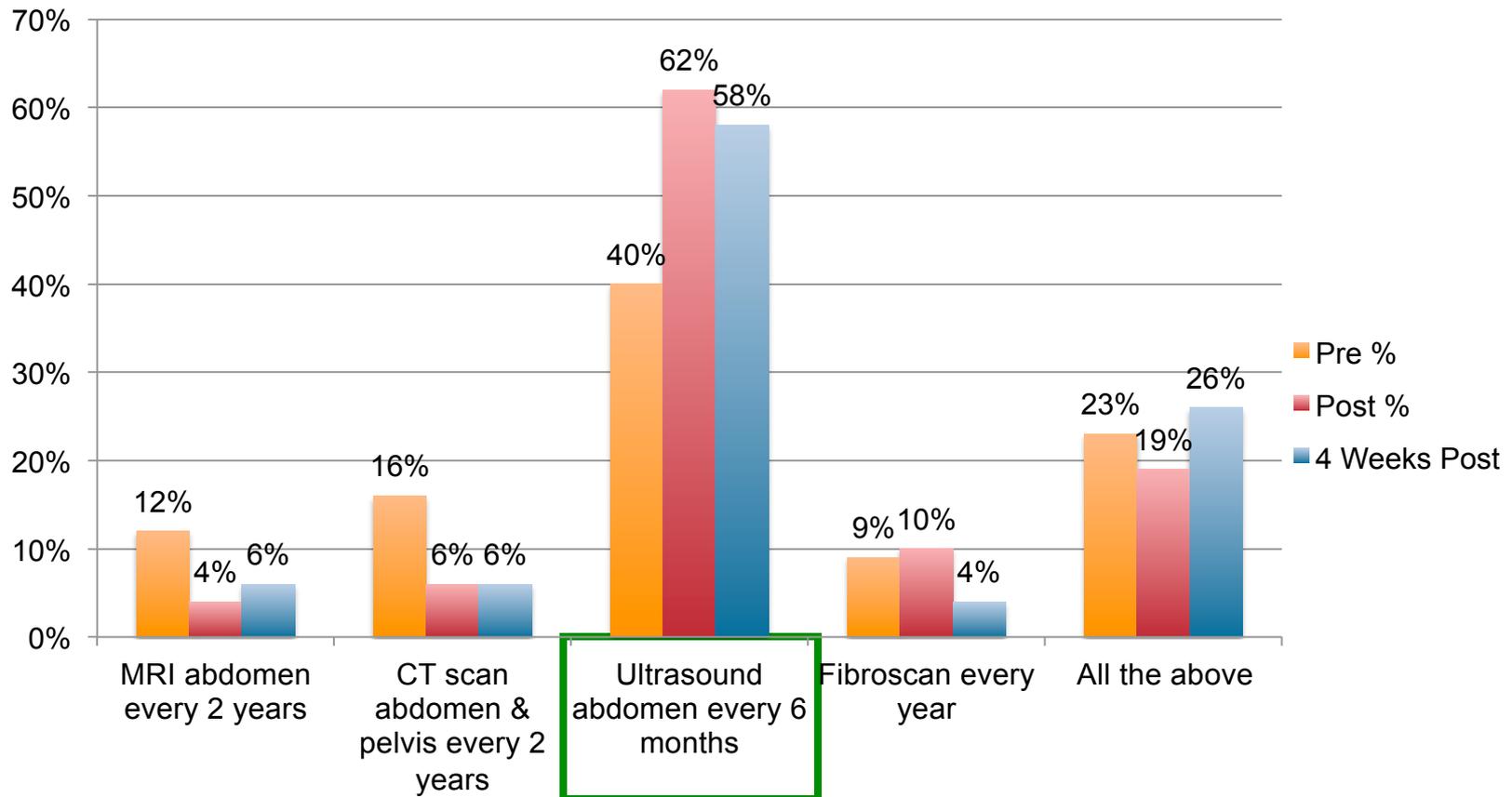

Pre N= 245   Post N= 236
4 Week Post N = 50

Green highlight indicates significant difference between pre and post testing.

Four Week Case Study Questions
(boxed answer is correct)

68 year old Hispanic woman with Metabolic syndrome has new onset ascites and was hospitalized recently for fluid overload. Blood tests show serum albumin of 2.4, platelets of 98k and upper endoscopy which showed grade 2 varices. She underwent a transjugular liver biopsy which shows stage 4 fibrosis.

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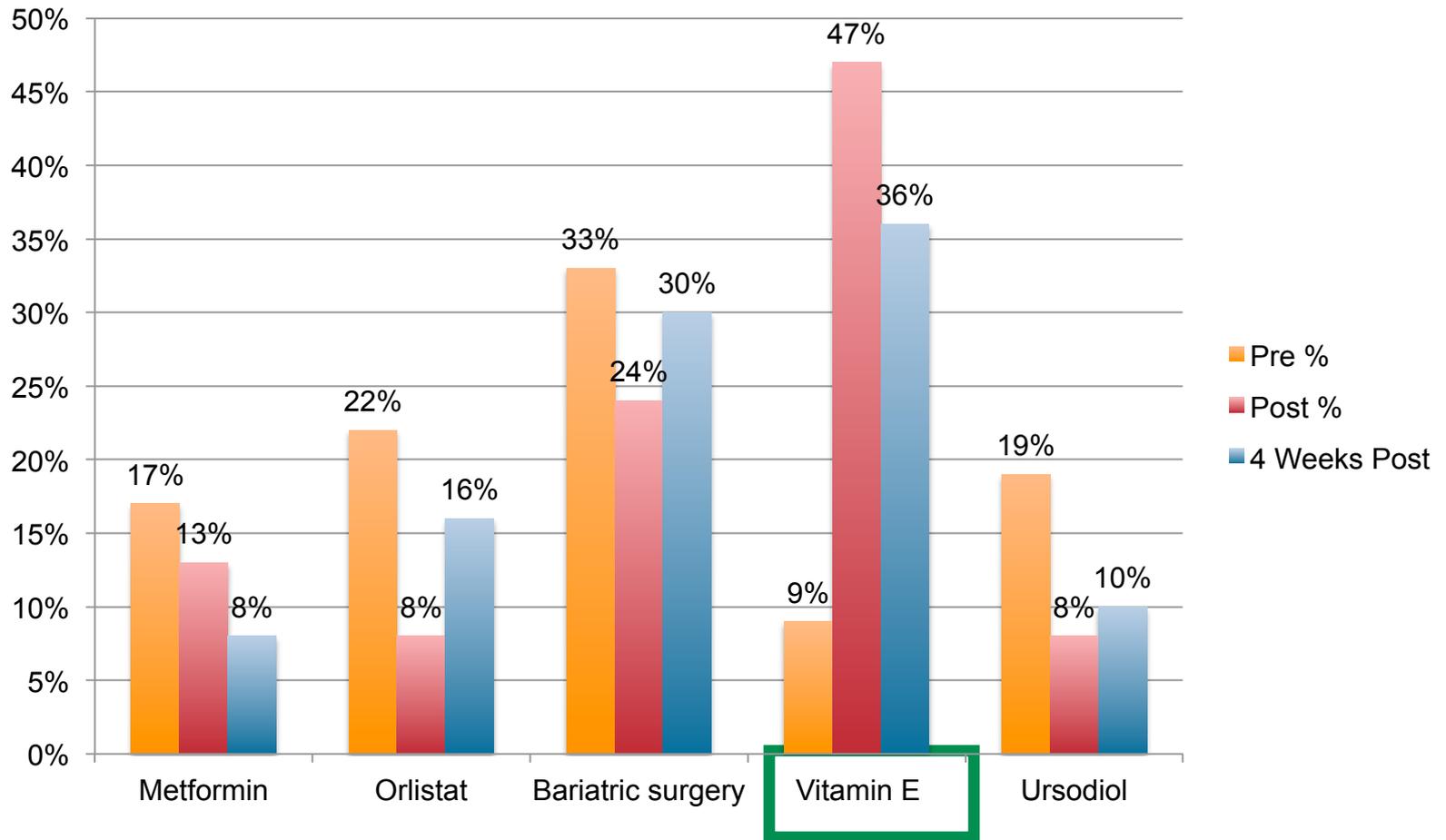
Pre N= 230   Post N= 253

4 Week Post N = 50

Green highlight indicates significant difference between pre and post testing.

Four Week Case Study Questions
(boxed answer is correct)

55 year old non-diabetic woman is recently diagnosed with NASH and advanced fibrosis (stage 3) on liver biopsy. You recommend aggressive life-style modifications but the patient was unable to lose > 1% of her body weight over a period of 1 year.

Given the presence of advanced fibrosis in the setting of NASH, which of the following additionally would you recommend in her management that would improve her liver histology? (Learning Objective 4)
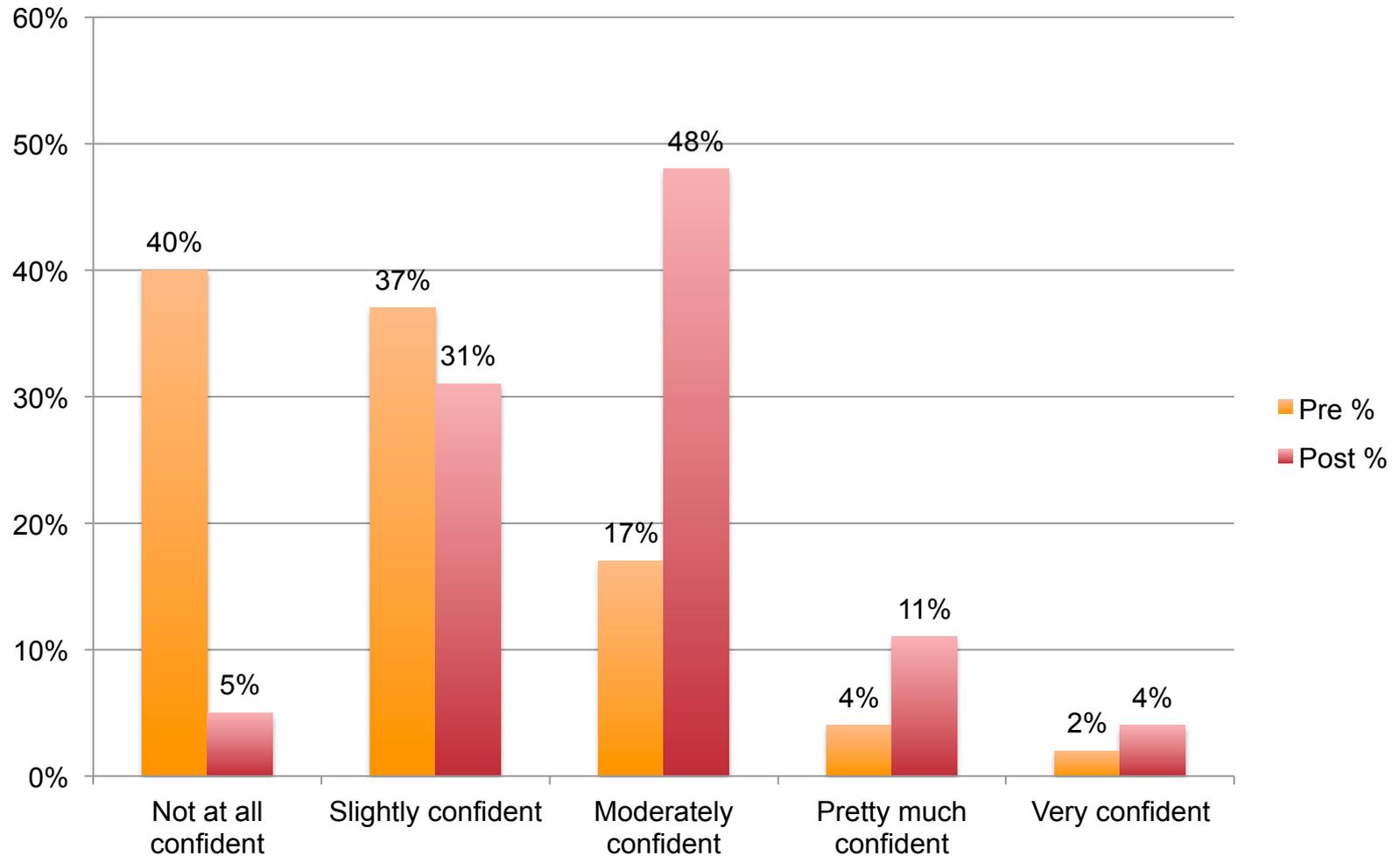

Pre N= 218 Post N= 242
    4 Week Post N = 50

Green highlight indicates significant difference between pre and post testing.

Nonalcoholic Steatohepatitis:
Identification and Evolving Treatment Strategies
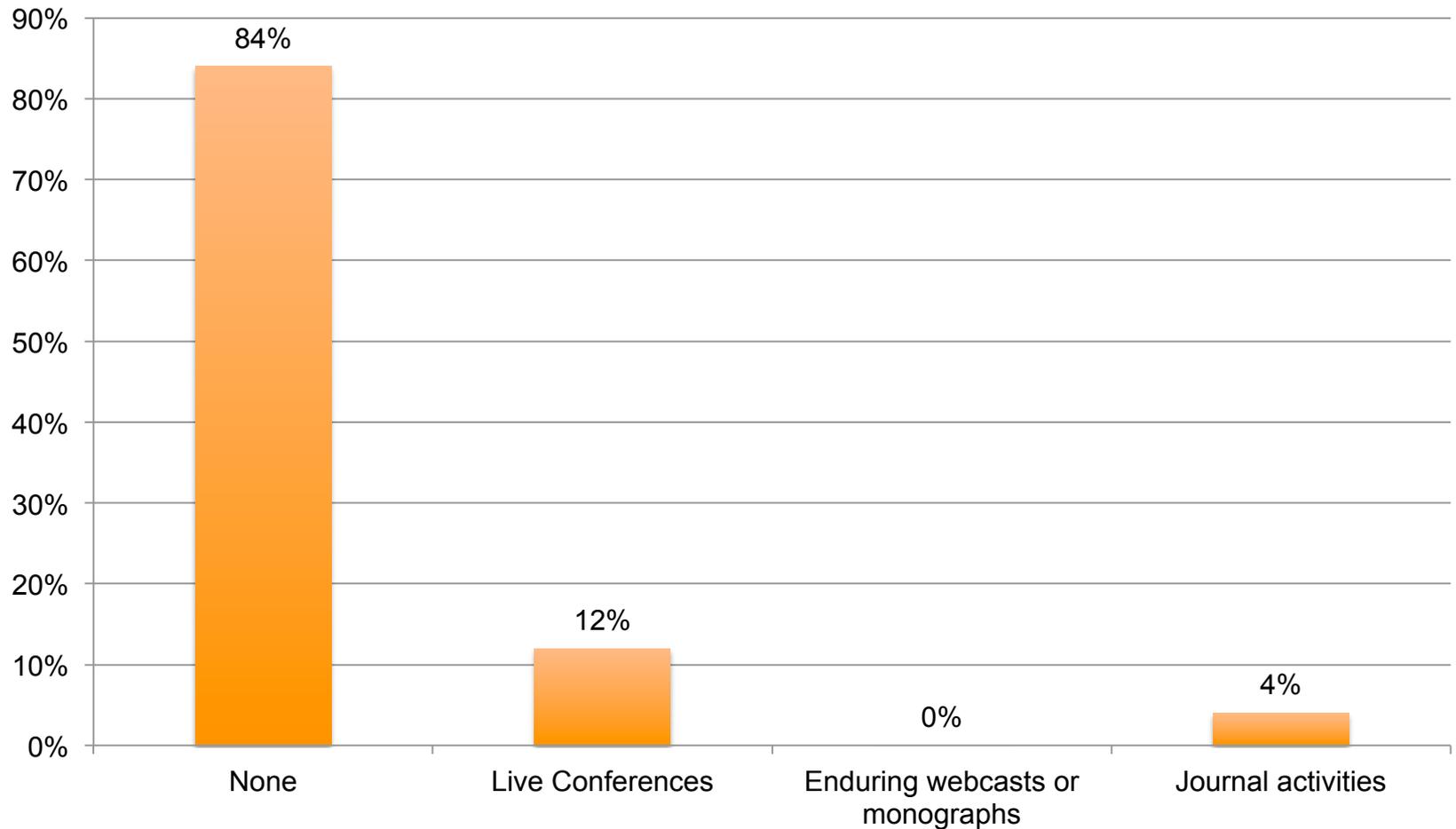
On a scale of 1 to 5, please rate how confident you would be treating a patient with non-alcoholic steatohepatitis:

Pre N= 248   Post N= 261

Nonalcoholic Steatohepatitis:
Identification and Evolving Treatment Strategies

Describe/list any other educational activities that you attended in the last month concerning the treatment of Nonalcoholic Steatohepatitis?

4 Weeks Post N= 50

Nonalcoholic Steatohepatitis:
Identification and Evolving Treatment Strategies

What specific skills or practice behaviors have you implemented for patients with Nonalcoholic Steatohepatitis since this CME activity? (Comments received from attendees at 4 week follow up)

- Monitoring patients more carefully
- Treatment targets are more specific in the patients with NALFD and NASH
- Recommending life style modification and adding vitamin E supplement in treatment regimen for fatty liver
- Identifying those with NASH
- Encouraged caffeinated coffee and other dietary changes
- Cautiously following liver enzymes in patients and encouraging weight loss and exercise
- Successfully guided patient to an exercise program, dietician, and regular monitoring to achieve 75 lb weight loss
- Understand the importance of screening and evaluating each and every patient
- Feel I have new assessment skills
- Using vitamin E and GLP injectables
- Ordering liver ultrasound on patients at high risk

Nonalcoholic Steatohepatitis:
Identification and Evolving Treatment Strategies

What specific barriers have you encountered that may have prevented you from successfully implementing strategies for patients with Nonalcoholic Steatohepatitis since this CME activity?
(Comments received from attendees at 4 week follow up)

- Cost for recommended bariatric surgery
- I don't see many people with NASH at this time
- Patients that are non-compliant
- Continued ETOH use, high fat/caloric diet and no exercise routine
- Getting patients to take the risk factors seriously and implement lifestyle changes
- The need for weight loss
- Time and patient adherence
- Insurance coverage
- Cost for uninsured
- Lack of patient follow through
- Limitation in practice setting
- Patient reluctance to proceed with testing and referrals due to finances
- Insurance approval and socio-economic conditions

Discussion and Implications
Nonalcoholic Steatohepatitis:
Identification and Evolving Treatment Strategies

The need for continued education in the identification and treatment of Nonalcoholic Steatohepatitis was demonstrated based on literature reviews and surveys completed prior to the conference series. Attendee knowledge was assessed at 3 points for this program: prior to the lecture, immediately following the lecture and again at 4 weeks after the conference. The results indicate a statistically significant improvement in knowledge in all 4 of the areas tested. Specifically, as a result of this lecture, participants: more easily recognize patients at risk for NASH; understand that a liver biopsy is the gold standard for distinguishing NAFLD from NASH; recognize that abdominal ultrasound every 6 months is appropriate to monitor a patient with decompensated cirrhosis for hepatocellular carcinoma; and understand that Vitamin E may be useful to improve liver histology in the setting of advanced fibrosis due to NASH.

Data obtained from participants 4 weeks after the program demonstrated some decline in learning from the post-test scores but continued improvement from pre-test scores in all areas. These results suggest that nearly all of the learning objectives for this activity were effectively addressed with attendees.

Data obtained from participants 4 weeks after the program demonstrated some decline in learning from the post-test scores but still significant improvement from the pre-test scores. Persistent gaps in knowledge exist: recognizing patients at risk and who to screen more carefully for NASH, strategies for monitoring patients with cirrhosis for hepatocellular carcinoma, and the role and timing of Vitamin E and other evolving treatment options.

Discussion and Implications
Nonalcoholic Steatohepatitis:
Identification and Evolving Treatment Strategies

Participants indicated a significant overall increase in self-reported confidence levels in the management of a patient with Nonalcoholic Steatohepatitis. Moderate to very confident levels rose from 23% to 63% by the end of the program. 31% of learners that were not involved with the diagnosis or management of patients with NAFLD or NASH are now thinking of it and 49% are planning on changing what they do as a result of this course. After the program, 90% of participants indicated that they are likely to utilize information learned from this presentation in their practice and 86% indicated that they had made changes 4 weeks after the program.

Attendees indicated multiple new, specific, practice behaviors they implemented as a result of this program that included identifying and monitoring patients more closely, advising diet and lifestyle changes, adding Vitamin E, caffeinated coffee, and GLP-1 RAs, and ordering liver ultrasounds for patients at high risk. 84% of respondents indicated that they had not participated in any other educational activities suggesting that their behavior changes were most likely a result of this program. Barriers to care included patient non-compliance, continued alcohol use with high caloric diet and no exercise, lack of insurance coverage, time limitations and difficulty getting patients to lose weight.

The notable changes in post test scores signify a clear gap in knowledge and an unmet need among primary care clinicians. Persistent gaps in knowledge persist across all areas indicating that additional education on Nonalcoholic Steatohepatitis screening and management is necessary for primary care clinicians.