Evaluation of EUS-FNA Cytopathology to Improve Sensitivity

EUS-guided FNA (EUS-FNA) with cytologic analysis yields a diagnostic accuracy that varies from 60 to 90%, with a specificity near 100% in pancreatic carcinoma. To determine the sensitivity and specificity of detection of chromosomal abnormalities by fluorescence in situ hybridization (FISH), analysis was studied with selective use of FISH in patients with inconclusive on-site cytopathology results to note possible improvement in the sensitivity of EUS for malignancy.

Consecutive patients were reviewed, with suspected pancreatic malignancy, nonrandomized cohort study, with final diagnosis based on either surgical biopsy or disease progression on extended follow-up or death.

A total of 212 EUS examinations were performed in 206 patients for pancreatic lesions in an academic center, tertiary care referral cancer center type. This was carried out in a 24-month period (January 2009 - December 2010). FISH analysis was done for 69 patients with inconclusive or not available on-site cytology results. FISH was carried out for polysomy of chromosomes 3, 7, 17, and deletion of 9p, 21.

Sixty-nine patients completed a study cohort, 54 with malignancy and 15 with benign disease. Sensitivity from malignancy of cytology, FISH analysis, and the combination was 61%, 74%, and 85%, respectively. FISH detected an additional 13 cases of pancreatic adenocarcinoma missed by cytology. There were no false-positive FISH analyses in 15 patients with benign disease. No major complications occurred from EUS-FNA.

It was concluded that in patients with suspected pancreatic cancer, FISH analysis can detect additional cases missed by cytology without compromising specificity and should be considered when cytology is negative for malignancy in patients with a known pancreatic mass. The limitations of this study were single-center with limited number of patients with benign disease.


Progression of Advanced Chronic Hepatitis C

In order to evaluate the incidence of liver disease progression among subjects with histologically advanced, but compensated chronic hepatitis C, the "Hepatitis C Antiviral Long-Term Treatment Against Cirrhosis" trial was carried out. This was a randomized study of 3, 5 years of maintenance PEG Interferon treatment on liver disease progression among patients who had not cleared virus on therapy with PEG Interferon and Ribavirin.

Patients on that study followed subsequently off therapy, with evidence that maintenance PEG Interferon treatment did not alter liver disease progression. Analysis of treatment of those patients and control patients together was carried out. Among 1,050 subjects (60% advanced fibrosis, 40% cirrhosis), the rate of progression to cirrhosis was determined over 4 years and of clinical outcomes over 8 years.

Among patients with fibrosis, the incidence of cirrhosis was 9.9% per year. A total of 679 clinical outcomes occurred among 329 subjects. Initial clinical outcomes occurred more frequently among subjects with cirrhosis (7.5% per year), than subjects with fibrosis (3.3% per year).

Child-Turcotte-Pugh (CTP) Score greater than 7 was the most common first outcome, followed by hepatocellular carcinoma. After the CTP Score of 7 or more, the rate of subsequent events increased to 12.9% per year, including a death rate of 10% per year. Baseline platelet count was a strong predictor of all clinical outcomes. During the 8 years of followup, death or liver transplantation occurred among 32% of the patients with advanced cirrhosis and 31.5% with cirrhosis.

It was concluded that among patients with advanced hepatitis C who failed PEG Interferon and Ribavirin therapy, the rate of liver-related outcomes, including death and liver transplantation, is high, especially once the CTP Score reaches at least 7.


Entecavir for HBV with a Partial Virological Response

To investigate the long-term efficacy and safety of Entecavir (ETV) in nucleoside or nucleotide analogue-naive chronic hepatitis B (CHB) patients, particularly in those with detectable HBV DNA after 48 weeks in whom treatment adaptation is suggested by current guidelines, a multicenter cohort study was carried out. A total of 333 CHB patients were treated with...
ETV monotherapy. Of these, 243 patients were naive, whereas 90 were not. Virologic response (VR) with HBV DNA less than 80 international units/milliliter, was achieved in 48%, 76% and 90% of hepatitis Be antigen-positive (HBeAg) and in 89%, 98%, and 99% of HBeAg-negative naive patients at weeks 48, 96, and 144, respectively.

A total of 36 of 175 (21%) naive patients with at least 48 weeks of followup had a detectable load at week 48 (partial virological response (PVR). A total of 29 (81%) patients with PVR reached VR during prolonged ETV monotherapy and none of them developed ETV resistance. Among 22 patients with HBV DNA less than 1,000 international units per milliliter at week 48, VR was achieved in 21 (95%) patients, compared with 8 of 14 (57%) patients with HBV DNA greater than 1,000 international units.

Continuous HBV DNA decline was observed in most patients without VR during followup and in 3 patients, adherence was suboptimal. According to the treating physician, ETV was safe and did not affect renal function or cause lactic acidosis.

It was concluded that ETV monotherapy can be continued in NA-naive patients with detectable HBV DNA at week 48, particularly in those with a low viral load because long-term ETV leads to a virologic response in the vast-majority of patients.


**Obesity and Clinical Decompensation in Cirrhosis**

Obesity is associated with an aggressive course in chronic viral hepatitis. In order to evaluate its impact in the development of clinical decompensation (CD) in patients with established cirrhosis, its role in relationship to other recognized predictors, and the development of CD with compensated cirrhosis was evaluated.

The study population was a subset of patients included in a randomized trial of beta-blockers in the prevention of varices, in whom data on BMI was available. There were 161 patients with compensated cirrhosis. Laboratory tests and portal pressure were assessed on inclusion. Patients were followed until CD, or until September 2002. All together, 29% had a normal BMI, 40% were overweight, and 30% were obese. In a median follow-up of 59 months, CD occurred in 48 of 161 (30%) patients with an increasingly higher rate according to BMI group (15% with normal BMI, 31% in overweight, 43% in obese patients). The actuarial probability of developing CD was significantly higher in the abnormal BMI groups.

In a multivariate model that included parameters previously identified as being predictive of CD (HVPG, albumin, MELD, etiology and treatment group, BMI was an independent predictor of decompensation, together with HVPG and albumin.

It was concluded that obesity has a deleterious effect on a natural history of compensated cirrhosis of all etiologies, independent of portal pressure and liver function. Weight reduction may be a valuable therapeutic measure in this patient population.


Murray H. Cohen, D.O., “From the Literature” Editor, is on the Editorial Board of *Practical Gastroenterology*
OraSure Technologies Receives CLIA Waiver for OraQuick® HCV Rapid Test

BETHLEHEM, PA. OraSure Technologies, Inc. (NASDAQ:OSUR) announced that the U.S. Food and Drug Administration (“FDA”) has granted a waiver under the Clinical Laboratory Improvement Amendments of 1988 (“CLIA”) for its OraQuick® HCV Rapid Antibody Test for use with fingerstick whole blood and venous whole blood specimens.

The OraQuick® HCV Rapid Antibody Test is the first and only FDA-approved rapid test for the detection of antibodies to the hepatitis C virus (“HCV”). The test, which utilizes the OraQuick® technology platform, provides results in 20 minutes. With this waiver, the OraQuick® HCV test now can be used by more than 180,000 sites in the United States to test persons who are at risk for hepatitis C or have signs or symptoms of hepatitis. These sites now extend to facilities that can perform CLIA-waived tests, such as outreach clinics, community-based organizations and physician offices.

“Today, more than 4 million Americans are infected with hepatitis C and the vast majority do not know it,” said Dr. Willis C. Maddrey, President of the Chronic Liver Disease Foundation. “Hepatitis C is a leading cause of chronic liver disease, cirrhosis and liver cancer. However, new therapies are now available that can effectively treat a high percentage of people with HCV infection, making expanded and accessible testing for HCV a critical step in fighting this epidemic.”

“A CLIA waiver for our OraQuick® HCV test represents a critical milestone in our quest to make the test available to the widest possible range of at risk individuals in the U.S.,” said Douglas A. Michels, President and Chief Executive Officer of OraSure Technologies. “The CLIA waiver will enable healthcare providers, those on the front lines of fighting this devastating disease, to use this simple and accurate test in physician offices and outreach settings so more individuals infected with hepatitis C can be diagnosed and treated.”

As previously announced, OraSure has entered into agreements with Merck & Co. (NYSE:MRK) to collaborate on the development and promotion of the OraQuick® HCV test. Under these agreements, Merck will provide detailing and other promotional support for the test in the physicians’ office markets in the United States and internationally. The approval of the CLIA waiver will now enable physicians to utilize the test in their office settings.

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DNA Genotek Inc., the Company also is a leading provider of oral fluid sample collection, stabilization and preparation products for molecular diagnostic applications. OraSure’s portfolio of products is sold globally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, research and academic institutions, distributors, government agencies, physicians’ offices, and commercial and industrial entities. The Company’s products enable healthcare providers to deliver critical information to patients, empowering them to make decisions to improve and protect their health. For more information on OraSure Technologies, please visit www.orasure.com.

**STERIS CORPORATION**
**INTRODUCES AMSCO® V-PRO® maX**
**LOW TEMPERATURE STERILIZATION SYSTEM**

*Newest vaporized hydrogen peroxide system offers departments a flexible new cycle and unique capabilities*

MENTOR, Ohio STERIS Corporation, a pioneer in low temperature sterilization, has launched the latest advance in its V-PRO line of healthcare sterilizers. The Amsco V-PRO maX Low Temperature Sterilization System offers three cycles and a number of advancements that enable healthcare providers to enhance overall processing performance, reduce inventory, save time and money, and ensure that patients consistently receive a high level of care.

“We continually seek to develop features and functions that make a meaningful difference in the daily workflow of our Customers,” said Renee Brown, product manager for the Infection Prevention Technologies division at STERIS. “In this case, the new V-PRO maX system offers more than advanced features; it integrates them into a high-performance whole that helps users achieve benefits greater than the sum of the parts. Specifically, the V-PRO maX benefits include potential gains in loading, processing and scheduling versatility, improved workflow speed and efficiency, and precedent-setting low-temperature sterile processing productivity.”

**Three cycle options**

In addition to the V-PRO maX Lumen Cycle, which processes up to 20 stainless steel lumens in 55 minutes, and Non Lumen Cycle, which is validated to process daVinci® robotic and other non-lumened devices in 28 minutes, this new sterilizer offers the Flexible Cycle, which completes in 35 minutes. This versatile cycle can process loads containing either two single or dual channel surgical flexible endoscopes/bronchoscopes, or one single/dual channel surgical flexible endoscope plus a robust non-lumened load (total load 24 pounds). Having three easy-to-use cycle options allows a department the flexibility to manage load types and workflow that synchronizes optimally with the daily procedure schedule. The unmatched versatility of these three cycles also gives departments the ability to use V-PRO maX systems to fulfill many of their low-temperature processing needs.

**More above-the-curve benefits**

- The V-PRO maX system provides other benefits that are also a giant leap forward for users:
  - Low sensitivity to moisture minimizes aborted cycles, which saves time and money and enables reliable device turnaround.**
  - The 136-liter chamber enables users to process twice the number of stainless steel lumened devices per cycle than competitive units.***
  - The V-PRO maX system uses a 59% concentration of hydrogen peroxide to sterilize, compared to up to 94% in other systems. This lower concentration reduces the risk of device and instrument damage.
  - The by-products of the V-PRO maX process are 100% biodegradable.
  - The new, larger control display is very easy to read, and new control features make it easy to navigate and use. The new streamlined design includes a pull-and-push ergonomic door that makes loading easy. When used in accordance with its full instructions for use, the new V-PRO maX Low Temperature Sterilization System is designed to simplify department operations, reduce workload and increase efficiency.

(continued on page 66)
Since it offers outstanding material compatibility and sterilization power, this system can help make sterile processing departments more productive, consistent and dependable.

*daVinci® is a registered trademark of Intuitive Surgical, Inc.

**A vacuum pump is used to remove excess moisture during the conditioning phase.

***As of October 1, 2011, STERRAD 100NX and NX systems are cleared to process 10 stainless steel lumens per load. The V-PRO maX system is cleared to process 20 stainless steel lumens per load.

Transplant Candidates Seek Best Quality Livers, Even if it Means Waiting Longer

U-M researcher finds patients would rather be on waiting list than accept an organ with higher risk of failure

More than 42 percent of patients would choose to remain on the waiting list rather than accept a “lower quality” liver according to the study’s lead author Michael L. Volk, M.D., M.S., assistant professor in U-M’s Department of Internal Medicine, Division of Gastroenterology.

Research from Volk and his colleagues will appear in the December issue of Liver Transplantation, a journal published by Wiley-Blackwell on behalf of the American Association for the Study of Liver Diseases.

As of November 30, the Organ Procurement and Transplantation Network (OPTN) reports that 16,124 candidates are on the waiting list to receive a liver, with only 5,375 deceased donor organs recovered through August. Additionally, there is a large variation in quality of deceased donor livers, which is based on donor characteristics such as age, cause of death, and ischemia time. Previous research has shown that donor characteristics can make the difference between a 20 to 40 percent risk of graft failure by three years following transplantation.

“Organ quality is an important issue for all liver transplant candidates, increasingly so, given the aging donor pool and more frequent use of organs that carry a higher risk of failure,” says Volk, who is a hepatology specialist. “The decision to accept or pass on an organ could mean the difference between life and death for patients with end-stage liver disease. Communication of the risks versus benefits of accepting a ‘lower quality’ organ is critical, and understanding patient views on the subject is essential for physicians caring for transplant candidates.”

For the current study, researchers tested presentation formats for communicating organ quality risks to patients, and factors that might influence patients’ willingness to accept higher-risk organs. First, the team conducted interviews with ten patients on the waiting list for liver transplantation to determine their knowledge of organ quality and preferences for accepting organs with greater risk of failure. Based on qualitative information obtained from interviews, the team created a web-based survey which 95 candidates completed.

The findings show that patients are reluctant to accept higher-risk organs. Of those completing the survey, 58 percent would only accept organs with a 25 percent (or less) risk of graft failure and 18 percent would only accept the lowest possible risk of 19 percent at three years following transplantation.

Women were slightly more accepting of high-risk organs than men. Researchers found that risk tolerance was increased by presenting organ quality as “average quality” rather than “best quality,” and by providing feedback about the implications of these preferences on the likelihood of receiving a transplant. Additionally, 83 percent of candidates were found to prefer an equal or dominant role in deciding whether to accept a higher-risk organ. This finding is striking given that, in most transplant centers, patient involvement in these decisions is minimal.

“Up until now, it has not been clear how much patients want to be involved in this complicated decision,” says Volk.

“Furthermore, explaining the intricacies of this topic to sick patients is easier said than done. Our findings offer transplant physicians some useful guidelines for how to council transplant candidates on issues of organ quality.”

The authors suggest future studies are needed to develop validated patient education tools that will enhance discussions between physicians and patients in need of liver transplantations.

Additional authors: All from U-M: Rachel S. Tocco, research specialist in the Department of Physical Medicine and Rehabilitation; Shawn J. Pelletier, M.D., associate professor of Surgery; Brian J. Zikmund-Fisher, Ph.D., research assistant professor in Department of Internal Medicine and assistant professor of Health Behavior and Education in the School of Public Health; and Anna S. Lok, M.D., F.R.C.P., Alice Lohman Andrews Research Professor in Liver Disease and professor in the Department of Internal Medicine.

For more information contact healthnews@wiley.com.
MEETINGS CALENDAR

January 20 & 21, 2012
AGA Clinical Congress of Gastroenterology and Hepatology
Miami, FL. Take advantage of this comprehensive, highly-relevant meeting for updating your clinical knowledge, earning MOC points and CME, and improving your ability to run a successful practice. By attending, you'll have direct access to a world-renowned faculty in a small, relaxed setting that encourages faculty-attendee interaction. Network with the expert faculty and connect with other like-minded GI physicians and health-care professionals from a variety of practice settings. For more information visit: www.gastro.org

May 18-23, 2012
SGNA 39th Annual Course
Phoenix, AZ. The Society of Gastroenterology Nurses and Associates 39th Annual Course is a chance for you to join and collaborate with your fellow GI/endoscopy professionals, resulting in professional growth and development. Learn more about the following opportunities you can take advantage of: Unique networking opportunities, Exciting general sessions, Business meetings and ABCGN certification.
SGNA is a professional organization of nurses and associates dedicated to the safe and effective practice of gastroenterology and endoscopy nursing. SGNA carries out its mission by advancing the science and practice of gastroenterology and endoscopy nursing through education, research, advocacy, and collaboration, and by promoting the professional development of its members in an atmosphere of mutual support.
For more information visit: www.sgna.org

May 19-22, 2012
Digestive Disease Week
San Diego Convention Center, San Diego, CA. DDW is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. An average of 15,000 medical professionals attend the meeting each year. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA), the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW showcases thousands of abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. Mission: To present the highest quality research in gastroenterology, hepatology, GI endoscopy and GI surgery and to provide top quality, state-of-the-art education and networking opportunities to GI professionals from around the world.
For more information visit: http://www.ddw.org

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PRACTICAL GASTROENTEROLOGY CROSSWORD PUZZLE

by Myles Mellor

DOWN
1. Important factor in treating AKI
2. Average normal catabolic rate, for short
3. Stinging insect
5. Scientist who popularized the concept of a magic bullet
6. Aka fungal, of an infection
7. Abrupt decline in glomerular filtration rate, abbr.
8. First
9. Compass point, for short
15. Hot or cold drink
17. Stretch out
18. Longtime record label
19. The N in NHL
20. The basic structural unit of DNA or RNA
23. Prefix with chloride
24. Even so
27. Renal replacement therapy, for short
29. College e-mail address ender
30. “Law and Order” character in every series
31. Tech executive
32. Transmit
33. Procedure
34. Protease inhibitor from Merck
35. Protein produced by cells
36. Area nitrogen regeneration rate, for short
37. Type of chemotherapy
38. Injuries to living tissue
41. Relating to evolutionary development
45. Continue to exist
46. Kind of message, abbr.
47. Computer memory
48. Chemical ending
49. Drug now approved in the treatment of HCV

ACROSS
1. Old name for hepatitis C virus
4. It was a major advance in HCV treatment
10. Key executive
11. Word used in diabetes classification
12. Serum ______
13. Badge displays it
14. Marked with stripes
16. Well-known duct
21. Intend
22. Treating a disease with the identical disease agent
25. Cell areas containing RNA and DNA
26. Hospital area for emergencies, for short
28. Compass direction
30. Protease inhibitor from Merck
34. Half
36. Area nitrogen regeneration rate, for short
37. Type of chemotherapy
39. Injuries to living tissue
41. Relating to evolutionary development
45. Continue to exist
46. Kind of message, abbr.
47. Computer memory
48. Chemical ending
49. Drug now approved in the treatment of HCV

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