Dissecting the Decision

Investigators Discuss the Available Data and Clinical Factors That Shape the Management of Gastrointestinal Cancers

A special audio supplement to a CME symposium held during the 2017 Gastrointestinal Cancers Symposium featuring expert comments on the application of emerging research to patient care

Faculty Interviews

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From the publishers of:

Gastrointestinal Cancer™ UPDATE

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Gastrointestinal Cancer™ UPDATE

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A Continuing Medical Education Audio Program

OVERVIEW OF ACTIVITY

Colorectal cancer (CRC) is a common and potentially lethal type of cancer, and its clinical management is continuously evolving. Although "non-CRC" gastrointestinal (GI) tumors are less frequently encountered individually, the cancer-related deaths in these subcategories surpass those attributed to CRC. Recently published randomized, controlled studies have led to the emergence of novel biomarkers and new therapeutic targets and regimens, thereby altering existing management algorithms. A number of pivotal data sets illustrating the benefits of several novel agents indicate that additional therapeutic options may soon be available that will warrant consideration. In order to offer optimal patient care — including the option of clinical trial participation — the practicing medical oncologist must be well informed of these advances. This CME program uses one-on-one interviews with 2 leading GI clinical investigators who served as faculty at a recent satellite symposium to discuss cases and questions submitted by attendees. This program will assist practicing clinicians in formulating up-to-date and appropriate clinical management strategies.

LEARNING OBJECTIVES

- Appraise recent data on therapeutic advances and changing practice standards in colorectal, gastric, pancreatic and hepatocellular cancer, and integrate this information, as appropriate, into current clinical care.
- Develop a long-term care plan for individuals with metastatic CRC considering biomarker profile, exposure to prior systemic therapy, symptomatology, performance status and personal goals for treatment.
- Use HER2 status, clinical factors and patient perspectives to optimize the selection and sequence of systemic therapy for patients with locally advanced or metastatic gastric or gastroesophageal cancer.
- Consider age, performance status and other clinical and logistical factors in the selection of systemic therapy for patients with locally advanced or metastatic pancreatic cancer.
- Communicate the benefits and risks of existing and emerging systemic interventions to patients with locally advanced or metastatic hepatocellular cancer.
- Appraise the rationale for and clinical data with anti-PD-1 and anti-PD-L1 antibodies for patients with GI cancers.
- Describe the proposed mechanisms of action of and recall new data with investigational agents demonstrating promising activity in GI cancers, and use this information to counsel appropriate patients regarding participation in ongoing clinical trials.

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FACULTY — The following faculty (and their spouses/partners) reported relevant conflicts of interest, which have been resolved through a conflict of interest resolution process: **Dr Bendell** — Contracted Research: Abbott Laboratories, AbbVie Inc, Apexigen, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, Daiichi Sankyo Inc, Eisai Inc, EMD Serono Inc, Five Prime Therapeutics Inc, Forty Seven Inc, Genentech BioOncology, Gilead Sciences Inc, GlaxoSmithKline, Incyte Corporation, Kolltan Pharmaceuticals Inc, Leap Therapeutics Inc, Lilly, MacroGenics Inc, MedImmune Inc, Merck, Novartis, OncoMed Pharmaceuticals Inc, Onyx Pharmaceuticals, an Amgen subsidiary, Pfizer Inc, Roche Laboratories Inc, Sanofi Genzyme, Stemcentrx, Taiho Oncology Inc, Takeda Oncology, TG Therapeutics Inc. **Dr O'Neil** — Advisory Committee: Amgen Inc, Bayer HealthCare Pharmaceuticals, Genentech BioOncology; Speakers Bureau: Bayer HealthCare Pharmaceuticals.

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Interview with Johanna C Bendell, MD

Tracks 1-16

Interview with Bert H O'Neil, MD

Tracks 17-28

SELECT PUBLICATIONS

Becerra C et al. **Phase Ib/II study of cancer stem cell (CSC) inhibitor BBI608 combined with paclitaxel in advanced gastric and gastroesophageal junction (GEJ) adenocarcinoma.** *Proc ASCO* 2015;**Abstract 4069**.

Bendell J et al. **Cancer stemness inhibition and chemosensitization: Phase Ib/II study of cancer stemness inhibitor napabucasin (BBI-608) with FOLFIRI +/- bevacizumab (bev) administered to colorectal cancer (CRC) patients (pts).** Gastrointestinal Cancers Symposium 2017;**Abstract 593**.

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Elez E et al. **Results of a phase 1b study of the selective BRAF V600 inhibitor encorafenib in combination with cetuximab alone or cetuximab + alpelisib for treatment of patients with advanced BRAF-mutant metastatic colorectal cancer.** WCGC 2015;**Abstract LBA08**.

Hingorani SR et al. **Interim results of a randomized phase II study of PEGPH20 added to *nab*-paclitaxel/gemcitabine in patients with stage IV previously untreated pancreatic cancer.** Gastrointestinal Cancers Symposium 2016;**Abstract 439**.

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Hong DS et al. **Phase Ib study of vemurafenib in combination with irinotecan and cetuximab in patients with BRAF-mutated metastatic colorectal cancer and advanced cancers.** *Proc ASCO* 2015;**Abstract 3511**.

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Janjigian YY et al. **Checkmate 649: A randomized, multicenter, open-label, phase 3 study of nivolumab (Nivo) plus ipilimumab (Ipi) versus oxaliplatin plus fluoropyrimidine in patients (Pts) with previously untreated advanced or metastatic gastric (G) or gastroesophageal junction (GEJ) cancer.** Gastrointestinal Cancers Symposium 2017;**Abstract TPS213**.

Kang YK et al. **Nivolumab (ONO-4538/BMS-936558) as salvage treatment after second or later-line chemotherapy for advanced gastric or gastro-esophageal junction cancer (AGC): A double-blinded, randomized, phase III trial.** Gastrointestinal Cancers Symposium 2017;**Abstract 02**.

Kelly RJ et al. **CheckMate 577: A randomized, double-blind, phase 3 study of nivolumab (Nivo) or placebo in patients (Pts) with resected lower esophageal (E) or gastroesophageal junction (GEJ) cancer.** Gastrointestinal Cancers Symposium 2017;**Abstract TPS212**.

Le DT et al. **KEYNOTE-164: Phase 2 study of pembrolizumab for patients with previously treated, microsatellite instability-high advanced colorectal carcinoma.** *Proc ASCO* 2016;**Abstract TPS3631**.

Le DT et al. **Programmed death-1 blockade in mismatch repair deficient colorectal cancer.** *Proc ASCO* 2016;**Abstract 103**.

Melero I et al. **Nivolumab dose escalation and expansion in patients with advanced hepatocellular carcinoma (HCC): The CheckMate 040 study.** Gastrointestinal Cancers Symposium 2017;**Abstract 226**.

Nordlinger B et al. **Perioperative FOLFOX4 chemotherapy and surgery versus surgery alone for resectable liver metastases from colorectal cancer (EORTC 40983): Long-term results of a randomised, controlled, phase 3 trial.** *Lancet Oncol* 2013;14(12):1208-15.

Ohtsu A et al. **Onset of neutropenia as an indicator of treatment response in the phase III RECOURSE trial of TAS-102 vs placebo in patients with metastatic colorectal cancer.** *Proc ASCO* 2016;**Abstract 3556**.

Ongoing phase III trial of cobimetinib and atezolizumab in chemotherapy-refractory mCRC (COTEZO — IMBlaze 370). NCT02788279

Overman MJ et al. **Nivolumab ± ipilimumab in treatment (tx) of patients (pts) with metastatic colorectal cancer (mCRC) with and without high microsatellite instability (MSI-H): CheckMate-142 interim results.** *Proc ASCO* 2016;**Abstract 3501**.

Sangro B et al. **A randomized, multicenter, phase 3 study of nivolumab vs sorafenib as first-line treatment in patients (pts) with advanced hepatocellular carcinoma (HCC): CheckMate-459.** *Proc ASCO* 2016;**Abstract TPS4147**.

Siena S et al. **Trastuzumab and lapatinib in HER2-amplified metastatic colorectal cancer patients (mCRC): The HERACLES trial.** *Proc ASCO* 2015;**Abstract 3508**.

Suker M et al. **FOLFIRINOX for locally advanced pancreatic cancer: A systematic review and patient-level meta-analysis.** *Lancet Oncol* 2016;17(6):801-10.

Van Cutsem E et al. **Updated results of the MEK inhibitor trametinib (T), BRAF inhibitor dabrafenib (D), and anti-EGFR antibody panitumumab (P) in patients (pts) with BRAF V600E mutated (BRAFm) metastatic colorectal cancer (mCRC).** WCGC 2015;**Abstract LBA07**.

Venook AP et al. **Impact of primary (1°) tumor location on overall survival (OS) and progression-free survival (PFS) in patients (pts) with metastatic colorectal cancer (mCRC): Analysis of CALGB/SWOG 80405 (Alliance).** *Proc ASCO* 2016;**Abstract 3504**.

Wang-Gillam A et al; NAPOLI-1 Study Group. **Nanoliposomal irinotecan with fluorouracil and folinic acid in metastatic pancreatic cancer after previous gemcitabine-based therapy (NAPOLI-1): A global, randomised, open-label, phase 3 trial.** *Lancet* 2016;387(10018):545-57.

Related Video Program

Visit www.ResearchToPractice.com/GICancers17/Video to view video proceedings from the satellite meeting held during the 2017 Gastrointestinal Cancers Symposium and earn additional *AMA PRA Category 1 Credit™*.

Topics covered include:

- Important systemic treatment considerations for patients with pancreatic adenocarcinoma
- Current and future treatment of gastric and gastroesophageal cancer
- Systemic therapy in the multidisciplinary management of hepatocellular carcinoma; novel agents and strategies
- Biologic and clinical factors in the selection and sequencing of systemic therapy for patients with metastatic colorectal cancer
- Later-line management of progressive metastatic colorectal cancer
- Checkpoint inhibitors in the treatment of metastatic colorectal cancer

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POST-TEST

Dissecting the Decision: Investigators Discuss the Available Data and Clinical Factors That Shape the Management of Gastrointestinal Cancers

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **Data suggest a lack of activity of EGFR antibodies as initial therapy for patients with CRC whose primary tumors originated on the _____ side of the colon.**
   a. Left
   b. Right
   c. Neither a nor b

2. **Data reported from the Phase III RECOURSE trial of TAS-102 versus placebo for patients with refractory CRC demonstrated the onset of _____ to be a correlate of treatment response in patients who received TAS-102.**
   a. Diarrhea
   b. Hand-foot syndrome
   c. Neutropenia

3. **What is the approximate incidence of HER2-amplified mCRC?**
   a. 5%
   b. 20%
   c. 40%

4. **Interim data presented by Hurwitz and colleagues at the 2017 Gastrointestinal Cancers Symposium on the MyPathway trial evaluating pertuzumab and trastuzumab reported this chemotherapy-free regimen to be active in patients with heavily pretreated HER2-amplified CRC.**
   a. True
   b. False

5. **Which of the following is the mechanism of action of PEGPH20?**
   a. Anti-PD-1/PD-L1 antibody
   b. MEK inhibitor
   c. Recombinant human hyaluronidase enzyme

6. **A recent study published in *The New England Journal of Medicine* and subsequently updated at ASCO 2016 demonstrated that patients with _____ CRC experienced objective responses to treatment with the immune checkpoint inhibitor pembrolizumab.**
   a. Mismatch repair (MMR) proficient
   b. MMR deficient
   c. Both a and b

7. **MEK inhibitors may increase infiltration of CD8-positive T cells into tumors, which is the biologic rationale for combining them with anti-PD-1/PD-L1 checkpoint inhibitors for patients with microsatellite-stable mCRC.**
   a. True
   b. False

8. **The Phase III NAPOLI-1 trial evaluating nanoliposomal irinotecan (nal-IRI) with or without 5-FU/LV versus 5-FU/LV alone for patients with metastatic pancreatic cancer after disease progression on gemcitabine-based therapy _____ a clinical benefit with the addition of nal-IRI to 5-FU/LV compared to 5-FU/LV alone.**
   a. Demonstrated
   b. Did not demonstrate

9. **Napabucasin (BBI608) is a _____ under evaluation in combination with chemotherapy for patients with advanced gastric cancer and other solid tumors.**
   a. Anti-PD-1/PD-L1 inhibitor
   b. Cancer stemness inhibitor
   c. VEGF inhibitor

10. **Patients with advanced HCC and disease progression on sorafenib treated with regorafenib on the Phase III RESORCE trial _____ experience a benefit as compared to those who received placebo.**
    a. Did
    b. Did not

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Dissecting the Decision: Investigators Discuss the Available Data and Clinical Factors That Shape the Management of Gastrointestinal Cancers

Research To Practice is committed to providing valuable continuing education for oncology clinicians, and your input is critical to helping us achieve this important goal. Please take the time to assess the activity you just completed, with the assurance that your answers and suggestions are strictly confidential.

PART 1 — Please tell us about your experience with this educational activity

How would you characterize your level of knowledge on the following topics?

4 = Excellent 3 = Good 2 = Adequate 1 = Suboptimal

	BEFORE	AFTER
Effect of tumor location on selection of therapy for patients with mCRC	4 3 2 1	4 3 2 1
Identification of patients with metastatic pancreatic cancer appropriate for treatment with nanoliposomal irinotecan in combination with 5-FU/LV	4 3 2 1	4 3 2 1
Effectiveness of nivolumab as salvage treatment after second- or later-line chemotherapy for advanced gastric or gastroesophageal junction cancer	4 3 2 1	4 3 2 1
Results from the Phase III RESORCE trial and potential role of regorafenib in patients with relapsed/refractory HCC	4 3 2 1	4 3 2 1

Practice Setting:

⬭ Academic center/medical school ⬭ Community cancer center/hospital ⬭ Group practice
⬭ Solo practice ⬭ Government (eg, VA) ⬭ Other (please specify).....

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⬭ Create/revise protocols, policies and/or procedures
⬭ Change the management and/or treatment of my patients
⬭ Other (please explain): .....

If you intend to implement any changes in your practice, please provide 1 or more examples:

.....

The content of this activity matched my current (or potential) scope of practice.

⬭ Yes ⬭ No If no, please explain: .....

Please respond to the following learning objectives (LOs) by circling the appropriate selection:

4 = Yes 3 = Will consider 2 = No 1 = Already doing N/M = LO not met N/A = Not applicable

As a result of this activity, I will be able to:

- Appraise recent data on therapeutic advances and changing practice standards in colorectal, gastric, pancreatic and hepatocellular cancer, and integrate this information, as appropriate, into current clinical care. .....4 3 2 1 N/M N/A
- Develop a long-term care plan for individuals with metastatic CRC considering biomarker profile, exposure to prior systemic therapy, symptomatology, performance status and personal goals for treatment..... .....4 3 2 1 N/M N/A
- Use HER2 status, clinical factors and patient perspectives to optimize the selection and sequence of systemic therapy for patients with locally advanced or metastatic gastric or gastroesophageal cancer. .....4 3 2 1 N/M N/A
- Consider age, performance status and other clinical and logistical factors in the selection of systemic therapy for patients with locally advanced or metastatic pancreatic cancer .....4 3 2 1 N/M N/A

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

As a result of this activity, I will be able to:

- Communicate the benefits and risks of existing and emerging systemic interventions to patients with locally advanced or metastatic hepatocellular cancer. . . . . 4 3 2 1 N/M N/A
- Appraise the rationale for and clinical data with anti-PD-1 and anti-PD-L1 antibodies for patients with GI cancers. . . . . 4 3 2 1 N/M N/A
- Describe the proposed mechanisms of action of and recall new data with investigational agents demonstrating promising activity in GI cancers, and use this information to counsel appropriate patients regarding participation in ongoing clinical trials. . . . . 4 3 2 1 N/M N/A

Please describe any clinical situations that you find difficult to manage or resolve that you would like to see addressed in future educational activities:

.....

Would you recommend this activity to a colleague?

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PART 2 — Please tell us about the faculty and editor for this educational activity

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Faculty	Knowledge of subject matter	Effectiveness as an educator
Johanna C Bendell, MD	4 3 2 1	4 3 2 1
Bert H O'Neil, MD	4 3 2 1	4 3 2 1
Editor	**Knowledge of subject matter**	**Effectiveness as an educator**
Neil Love, MD	4 3 2 1	4 3 2 1

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Gastrointestinal Cancer™
UPDATE

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