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CLINICAL Colorectal Cancer

and Other Gastrointestinal
Malignancies

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A6 Clinical Skin Cancer: The Next Addition to Elsevier's Clinical Cancer (ECC) Journal Portfolio

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Original Studies

- 222 A Phase II Efficacy and Safety, Open-Label, Multicenter Study of Imprime PGG Injection in Combination With Cetuximab in Patients With Stage IV KRAS-Mutant Colorectal Cancer
Neil H. Segal, Purvi Gada, Neil Senzer, Michele A. Gargano, Myra L. Patchen, Leonard B. Saltz
Cetuximab alone is ineffective in KRAS-mutant colorectal cancer. Imprime PGG ($\beta(1,6)$ -[poly-(1,3)-D-glucopyranosyl]-poly- $\beta(1,3)$ -D-glucopyranose), a yeast-derived beta-glucan polymer, activates innate immune effector cells enabling recognition and killing of tumor coated by a complement-activating antibody, such as cetuximab. In this phase II study, immune therapy for KRAS-mutant colorectal cancer with Imprime PGG plus cetuximab was assessed. The combination was safe and compelling, albeit modest, clinical activity was shown.
- 228 Autologous Cytokine-Induced Killer Cells Improves Overall Survival of Metastatic Colorectal Cancer Patients: Results From a Phase II Clinical Trial
Hua Zhao, Yang Wang, Jinpu Yu, Feng Wei, Shui Cao, Xinwei Zhang, Nan Dong, Hui Li, Xiubao Ren

The therapeutic benefit of autologous cytokine-induced killer (CIK) therapy on metastatic colorectal cancer (mCRC) patients was still unknown. A total of 122 mCRC patients were randomized to this clinical study to evaluate the therapeutic benefits of CIK therapy. It showed that CIK cells with chemotherapy was well-tolerated and could improve the overall survival of mCRC patients.

236 Uracil-Tegafur and Oral Leucovorin Combined With Bevacizumab in Elderly Patients (Aged ≥ 75 Years) With Metastatic Colorectal Cancer: A Multicenter, Phase II Trial (Joint Study of Bevacizumab, Oral Leucovorin, and Uracil-Tegafur in Elderly Patients [J-BLUE] Study)

Tomohiro Nishina, Toshikazu Moriwaki, Mitsuo Shimada, Jun Higashijima, Yoshinori Sakai, Toshiki Masuishi, Mitsuharu Ozeki, Kenji Amagai, Yuji Negoro, Shunju Indo, Tadamichi Denda, Mikio Sato, Yuji Yamamoto, Go Nakajima, Minoru Mizuta, Ikuo Takahashi, Yoshinori Hiroshima, Hiroyasu Ishida, Takashi Maeba, Ichinosuke Hyodo

In the present phase II trial of 55 elderly patients (aged ≥ 75 years) with previously untreated metastatic colorectal cancer, we investigated the efficacy and safety of the combination of uracil-tegafur with oral leucovorin (UFT/LV) and bevacizumab. UFT/LV plus bevacizumab resulted in promising efficacy outcomes with mild toxicity and should be validated in future largescale studies of elderly patients.

243 PROSPECT Eligibility and Clinical Outcomes: Results From the Pan-Canadian Rectal Cancer Consortium

Dominick Bossé, Jamison Mercer, Soundouss Raissouni, Kristopher Dennis, Rachel Goodwin, Di Jiang, Erin Powell, Aalok Kumar, Richard Lee-Ying, Julie Price-Hiller, Daniel Y.C. Heng, Patricia A. Tang, Anthony MacLean, Winson Y. Cheung, Michael M. Vickers

The PROSPECT trial investigates the feasibility of avoiding chemoradiation in selected patients with locally advanced rectal cancer. We identified patients who met PROSPECT trial eligibility criteria and found favorable outcomes for eligible compared to ineligible patients. Our findings support the PROSPECT study design, as it selects a patient population in whom omission of radiotherapy should be actively investigated.

250 Feasibility of Capecitabine and Oxaliplatin Combination Chemotherapy Without Central Venous Access Device in Patients With Stage III Colorectal Cancer

Alexandra Lapeyre-Prost, Marine Hug de Larauze, Benoist Chibaudel, Marie Line Garcia, Veronique Guering-Meyer, Olivier Bouché, Eveline Boucher, Marc Ychou, Jérôme Dauba, Stéphane Obled, Astrid Lièvre, David Malka, Roger Faroux, Isabelle Bonnet, Julien Taieb, Thierry André, on behalf of the Groupe Coopérateur Multidisciplinaire en Oncologie, the Fédération Francophone de la Cancérologie Digestive, and the UNICANCER Investigators of the PRODIGE Intergroup

The use of a central venous access device (CVAD) for adjuvant XELOX (capecitabine, oxaliplatin) does not appear to be justified for all cases of stage III colon cancer. The feasibility of XELOX without a CVAD in the adjuvant setting for stage III patients was evaluated. Our results confirm the feasibility of this approach in 81.2% of patients for whom a CVAD was not placed before the first chemotherapy cycle.

257 Concomitant Administration of Proton Pump Inhibitors and Capecitabine is Associated With Increased Recurrence Risk in Early Stage Colorectal Cancer Patients

Julia Sun, Alastair I. Ilich, Christina A. Kim, Michael P. Chu, Grace G. Wong, Sunita Ghosh, Melanie Danilak, Karen E. Mulder, Jennifer L. Spratlin, Carole R. Chambers, Michael B. Sawyer

Proton pump inhibitor (PPI) use in conjunction with oral tyrosine kinase inhibitors have been shown to negatively impact efficacy. This retrospective study comparing PPI effects on capecitabine efficacy in early stage colorectal cancer patients found that concomitant PPI use significantly worsened 5-year recurrence-free survival. Patients requiring capecitabine dose reduction and discontinuation had worse 5-year recurrence free survival compared with control and dose-delay groups.

264 Analysis of Response-Related and Time-to-event Endpoints in Randomized Trials of Gemcitabine-Based Treatment Versus Gemcitabine Alone as First-Line Treatment of Patients With Advanced Pancreatic Cancer

Giuseppe Colloca, Antonella Venturino, Domenico Guarneri

The endpoints of trials of gemcitabine-based chemotherapy for metastatic pancreatic cancer were examined in 37 randomized trials. Progression-free survival was strongly related to overall survival in chemotherapy and bio-chemotherapy trials, although this correlation could have been influenced by the interval of radiologic evaluation. Among the response-related endpoints, the disease control rate seems the most promising.

**Available Exclusively Online at
www.clinical-colorectal-cancer.com**

- e65 Screening for Colorectal Cancer Using a Multitarget Stool DNA Test: Modeling the Effect of the Intertest Interval on Clinical Effectiveness**
Barry M. Berger, Paul C. Schroy, III, Tuan A. Dinh
Colorectal cancer (CRC) screening with a multitarget stool DNA test was recently approved by the Food and Drug Administration. We used clinical effectiveness modeling to compare test intervals of 1, 3, or 5 years on CRC incidence and related mortality to help inform screening guidelines. Our results showed that screening every 3 years provides reasonable performance at acceptable cost.
- e75 Peptide Patterns as Discriminating Biomarkers in Plasma of Patients With Familial Adenomatous Polyposis**
Lisa Agatea, Sara Crotti, Eugenio Ragazzi, Chiara Bedin, Emanuele Urso, Isabella Mammi, Pietro Traldi, Salvatore Pucciarelli, Donato Nitti, Marco Agostini
We use the mass spectrometry technique for the detection of circulating peptides in patients with familial adenomatous polyposis (FAP). We describe a FAP-specific fingerprint that allows early identification of the disease and neoplastic transformation. Our results are relevant because they could postpone preventive surgery as long as possible, improving the quality of life of patients with FAP.
- e93 Long-Term Health-Related Quality of Life in Patients With Rectal Cancer After Preoperative Short-Course and Long-Course (Chemo) Radiotherapy**
Lisette M. Wiltink, Remi A. Nout, Jochem R.N. van der Voort van Zyp, Heleen M. Ceha, Marta Fiocco, Elma Meershoek-Klein Kranenbarg, Andreas W.K.S. Marinelli, Cornelis J.H. van de Velde, Corrie A.M. Marijnen
Long-term health-related quality of life is compared between patients with rectal cancer preoperatively treated with long-course chemo radiotherapy (CRT) or with short-course radiotherapy. Apart from less satisfaction with urinary function reported by patients who had CRT, no clinically relevant differences in health-related quality of life and patient-reported symptoms between patients who had CRT and short-course radiotherapy were found at 5 years after rectal cancer treatment.
- e101 Therapeutic Evaluation of Biofeedback Therapy in the Treatment of Anterior Resection Syndrome After Sphincter-Saving Surgery for Rectal Cancer**
Zhonglin Liang, Wenjun Ding, Wei Chen, Zhongchuan Wang, Peng Du, Long Cui
The present retrospective study was designed to evaluate the effectiveness of biofeedback therapy for fecal incontinence in patients with anterior resection syndrome after low anterior resection for rectal cancer. Several associated factors that might influence therapeutic success were investigated. These factors could help predict the therapeutic outcomes and thus inform the risk/benefit decisions for such patients after sphincter-saving surgery.
- e109 Safety and Efficacy of Trifluridine/Tipiracil Monotherapy in Clinical Practice for Patients With Metastatic Colorectal Cancer: Experience at a Single Institution**
Daisuke Kotani, Kohei Shitara, Akihito Kawazoe, Shota Fukuoka, Yasutoshi Kuboki, Hideaki Bando, Wataru Okamoto, Takashi Kojima, Toshihiko Doi, Atsushi Ohtsu, Takayuki Yoshino
Little information is available regarding the safety and efficacy of trifluridine/tipiracil (TAS-102) monotherapy in clinical practice. A retrospective study of 55 patients at a single institution was performed to clarify the safety and efficacy of TAS-102 monotherapy in clinical practice. Our findings indicate that the safety and efficacy of TAS-102 seen in pivotal trials are maintained in clinical practice, regardless of the previous use of regorafenib.
- e117 Management of Epidermal Growth Factor Receptor Inhibitor-Induced Hypomagnesemia: A Systematic Review**
Di (Maria) Jiang, Kristopher Dennis, Andrew Steinmetz, Mark Clemons, Timothy R. Asmis, Rachel A. Goodwin, Michael M. Vickers
Hypomagnesemia is a common side effect of treatment with epidermal growth factor receptor inhibitor. Guidelines recommend intravenous magnesium replacement to treat this toxicity; however, our systematic review

has found little evidence to support this approach. Prospective studies are needed to define the best strategy to manage epidermal growth factor receptor inhibitor-induced hypomagnesemia.

e125 Primary Tumor Resection and Overall Survival in Patients With Metastatic Colorectal Cancer Treated With Palliative Intent

Shu Fen Wong, Hui Li Wong, Kathryn M. Field, Suzanne Kosmider, Jeanne Tie, Rachel Wong, Mark Tacey, Jeremy Shapiro, Louise Nott, Gary Richardson, Prasad Cooray, Ian Jones, Matthew Croxford, Peter Gibbs

The present study examined the effect of primary tumor resection on overall survival of patients with metastatic colorectal cancer (mCRC). A total of 690 de novo and 373 metachronous mCRC patients treated with palliative intent were identified. For patients with de novo mCRC, primary tumor resection at diagnosis does not significantly improve overall survival when adjusting for known major prognostic factors.

e133 Oxaliplatin-Induced Neuropathy: A Long-Term Clinical and Neurophysiologic Follow-Up Study

Panagiotis Kokotis, Martin Schmelz, Efthymios Kostouros, Nikolaos Karandreas, Meletios-Athanasios Dimopoulos

Acute oxaliplatin neurotoxicity and chronic sensory cumulative neuropathy were investigated in a long-term study of 31 consecutive patients with advanced colorectal cancer. Our results improve the knowledge of acute neurotoxicity and support the finding of the persistence of the sensory nerve deficits for years after the cessation of oxaliplatin therapy.