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September 14-17
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Patients with advanced esophageal cancer who receive radiation therapy alone experience less problems when swallowing compared to those who receive RT combined with chemotherapy

San Francisco, September 14, 2014—Radiation therapy (RT) alone is as effective in decreasing swallowing complications experienced by advanced esophageal cancer patients as RT combined with chemotherapy, thus allowing patients to forgo chemotherapy, according to research presented today at the American Society for Radiation Oncology's (ASTRO's) 56th Annual Meeting.

In this international study that included sites in Australia, New Zealand, Canada and the United Kingdom, researchers assessed the use of palliative chemotherapy combined with RT, or chemoradiotherapy (CRT), to provide relief from dysphagia. Dysphagia, or difficulty swallowing, is a common complication of advanced esophageal cancer and has been shown to be relieved with RT. The trial evaluated the effectiveness of RT alone versus CRT through patient-reported questionnaires that measured swallowing ability and quality of life, and through clinician-reported questionnaires that measured potential side effects and adverse events that affected the entire body.

A total of 220 patients were randomized to receive a course of palliative RT: 115 patients in Australia and New Zealand received 35 Gy in 15 fractions, and 105 patients in Canada and the United Kingdom received

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30 Gy in 10 fractions. Of those patients, 109 received only RT, and 111 received concomitant CRT including Cisplatin and 5FU.

Dysphagia was measured using the Mellow scoring system, which measures swallowing on a scale of 0 to 5 based on the patient's ability to swallow liquids or solids. Side effects were measured by clinicians using the Common Terminology Criteria for Adverse Events (CTCAE) v2, and quality of life was evaluated using two patient questionnaires—EORTC QLQ30 and oesophagus module (OES-18). The primary end point was the proportion of patients with improved dysphagia as measured at week 9 and maintained until week 13.

Of the patients who received RT alone, 67.89 percent of patients reported a more favorable dysphagia response (meaning decreased pain at any point) compared to 73.87 percent of patients who received CRT and showed a positive dysphagia response ($p=0.343$).

Gastrointestinal side effects were reported in the CRT patients, including nausea ($p=0.0019$) and vomiting ($p=0.0072$). The median survival was 203 days for patients who received RT alone and 210 days for patients who had CRT, demonstrating comparable survival prognosis for both groups.

"This study was the largest, randomized, phase three trial of advanced esophageal cancer and was a significant undertaking for a 'palliative care' trial, namely where the emphasis was on the best, yet simplest and least toxic treatment to alleviate pain," said lead author Michael Penniment, MBBS, MBA, FRANZCR, director of radiation oncology at Royal Adelaide Hospital in South Australia and the director of radiation oncology at Alan Walker Cancer Care Centre in Darwin, Australia. "It is common for chemotherapy to be prescribed for patients with advanced esophageal cancer, and this is based on the standard use of CRT in people with less advanced disease. However, some clinicians believe no treatment should be offered, assuming treatment is futile and potentially toxic. These results will allow us to simplify the treatment for patients who cannot be cured but who can expect an improvement in swallowing and quality of life as a result of RT alone; and these patients can be spared the extra toxicity and cost of chemotherapy."

The abstract, "Best Practice in Advanced Oesophageal Cancer: A Report on TROG 03.01 NCIC CTG ES.2 Multinational Phase III Study in Advanced Oesophageal Cancer (OC) Comparing Quality of Life (QoL) and Palliation of Dysphagia in Patients Treated with Radiotherapy (RT) or Chemo-Radiotherapy (CRT)," will be presented in detail during a scientific session at ASTRO's 56th Annual Meeting at 3:15 p.m. Pacific time on Sunday, September 14, 2014. To speak with Dr. Penniment, please call Michelle Kirkwood on September 14 – 17, 2014, in the ASTRO Press Office at the Moscone Center in San Francisco Center at 415-978-3503 or 415-978-3504, or email michellek@astro.org.

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ASTRO's 56th Annual Meeting, to be held at the Moscone Center in San Francisco, September 14-17, 2014, is the nation's premier scientific meeting in radiation oncology. The 2014 Annual Meeting is expected to attract more than 11,000 attendees including oncologists from all disciplines, medical physicists, dosimetrists, radiation therapists, radiation oncology nurses and nurse practitioners, biologists, physician assistants, practice administrators, industry representatives and other health care professionals from around the world. Led by ASTRO President Bruce G. Haffty, MD, FASTRO, a radiation oncologist specializing in breast cancer, the theme of the 2014 Meeting is "Targeting Cancer: Technology and Biology," and the Presidential Symposium, "Local-regional Management of Breast Cancer: A Changing Paradigm," will feature Jay R. Harris, MD, FASTRO, and Thomas A. Buchholz, MD, FASTRO, to highlight recent practice-changing, landmark studies and current developments in the local-regional management of breast cancer. ASTRO's four-day scientific meeting includes presentation of up to four plenary papers, 360 oral presentations, 1,862 posters and 144 digital posters in more than 50 educational sessions and scientific panels for 20 disease-site tracks. Three keynote speakers will address a range of topics including oncologic imaging, biology and targeting in oncology, and human error and safety concerns: Hedvig Hricak, MD, PhD, Chair of the Department of Radiology and the Carroll and Milton Petrie Chair at Memorial Sloan Kettering Cancer Center; Frank McCormick, PhD, FRS, DSc (hon), Professor Emeritus and the David A. Wood Distinguished Professor of Tumor Biology and Cancer Research of the University of California at San Francisco Helen Diller Family Comprehensive Cancer Center; and Sidney Dekker, PhD, MA, MSc, Professor and Director of the Safety Science Innovation Lab at Griffith University, Brisbane, Australia.

ABOUT ASTRO

ASTRO is the premier radiation oncology society in the world, with more than 10,000 members who are physicians, nurses, biologists, physicists, radiation therapists, dosimetrists and other health care professionals that specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, the Society is dedicated to improving patient care through professional education and training, support for clinical practice and health policy standards, advancement of science and research, and advocacy. ASTRO publishes two medical journals, International Journal of Radiation Oncology • Biology • Physics (www.redjournal.org) and Practical Radiation Oncology (www.practicalradonc.org); developed and maintains an extensive patient website, www.rtanswers.org; and created the Radiation Oncology Institute (www.roinstitute.org), a non-profit foundation to support research and education efforts around the world that enhance and confirm the critical role of radiation therapy in improving cancer treatment. To learn more about ASTRO, visit www.astro.org.

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2014 American Society for Radiation Oncology (ASTRO) 56th Annual Meeting
News Briefing, Monday, September 15, 2014, 11:00 a.m. Pacific time

Scientific Session: Sunday, September 14, 2014, 3:15 – 4:45 p.m. PT, the Moscone Center

CT-03 **Best Practice in Advanced Oesophageal Cancer: A Report on TROG 03.01 NCIC CTG ES.2 Multinational Phase III Study in Advanced Oesophageal Cancer (OC) Comparing Quality of Life (QoL) and Palliation of Dysphagia in Patients Treated with Radiotherapy (RT) or Chemo-Radiotherapy (CRT)**

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Purpose/Objective(s): RT is known to relieve dysphagia of advanced oesophageal cancer, there is no data from randomised phase III trials determining response, toxicity, or role of palliative CRT. Aims 1) to establish effective and least toxic treatment for symptom relief of advanced OC 2) determine effects of common cancer treatments on QoL and end of life care 3) establish an evidence base for patient decision making regarding the optimal management for incurable OC.

Materials/Methods: 220 patients were randomised to receive a course of palliative RT [35 Gy in 15 fractions in Australia and New Zealand, (n=115) or 30 Gy in 10 fractions (n=105) in Canada and UK], or concomitant CRT with Cisplatin and 5FU (D1-4) (n=111). Dysphagia was measured using the Mellow score, toxicity using CTCAE v2, and QoL using EORTC QLQ30 and oesophagus module (OES-18). The primary end point was the proportion of patients with improved dysphagia as measured at week 9 and maintained until week 13.

Results: The patients receiving radiotherapy alone showed a dysphagia response (at any point) of 67.89% compared to chemotherapy response in 73.87% (p=0.343). There was increased gastro-intestinal toxicity in patients receiving CRT (nausea (p=0.0019) and vomiting (p=0.0072)). The median survival was 210 days for CRT and 203 days for RT alone. The baseline parameters of both groups were well matched at randomisation and although the results of the trial showed equally poor survival prognosis in both arms, there were some patients (n=21) still alive at 2 years post treatment.

Conclusions: CRT was associated with increased gastro-intestinal toxicity without any significant improvement in dysphagia response or median survival. Further analysis of QoL, toxicity and durable palliative response will be published. This multicentre trial reflects practice in several countries. RT alone remains an excellent tool for palliation of patients with advanced OC and should remain the standard of care.

Author Disclosure Block: M.G. Penniment: None. J.A. Harvey: None. R. Wong: None. S. Stephens: None. H. Au: None. C.J. O'Callaghan: None. A.B. Kneebone: None. S. Ngan: None. I.G. Ward: None. R. Roy: None. T. Sullivan: None. T. Nijjar: None. J. Biagi: None. L.A. Mulroy: None.