Embargoed until 3:15 p.m., CT, Sunday, October 18, 2015

Reduced intensity chemoradiotherapy may be as effective as current standard for patients with HPV-related oropharynx cancer

*Patients who received reduced dose experienced less side effects*

San Antonio, October 18, 2015— For some patients with human papilloma virus (HPV)-related cancer of the tonsils and tongue, reduced intensity radiation therapy (RT) and chemotherapy may be as effective as standard-dose radiation and chemotherapy, and result in less acute side effects, according to research presented today at the American Society for Radiation Oncology’s (ASTRO’s) 57th Annual Meeting.

The incidence of cancer at the base of the tongue and tonsil is rapidly increasing and thought to be caused by HPV infection. The standard treatment for patients with HPV-related squamous cell carcinoma of the oropharynx is a seven-week course of 70 Gy of RT, in conjunction with a high-dose (100 mg/m²) of the chemotherapy drug Cisplatin for three cycles. Although this standard chemoradiotherapy protocol results in excellent cancer control and survival among patients, it produces substantial adverse side effects, such as chronic, acute difficulties in talking or swallowing, which may require a feeding tube; dry mouth; painful inflammation of the mucous membranes and/or digestive tract; tooth decay and necrosis of the jawbone.
This prospective, multi-institutional, phase II study assessed the use of reduced intensity chemoradiotherapy among 43 patients with favorable risk HPV-associated oropharyngeal squamous cell carcinoma who had a minimal history of smoking. Radiation therapy was reduced by 16 percent, to a six-week course of 60 Gy, and the chemotherapy dose was reduced by 60 percent overall, with low doses (30 mg/m²) of Cisplatin delivered concurrently for six weeks.

After patients completed chemoradiotherapy, the tumor site was biopsied and any lymph node regions that were originally cancer-positive were removed in order to determine the treatment’s efficacy. Of the 43 patients studied, 37 of them (86 percent) had no residual invasive tumor and no residual lymph node metastasis. The cancer remaining in the other six patients was microscopic. Follow-up was conducted for six-to-36 months, with an average follow-up of 20.7 months, during which all patients were alive and had no evidence of cancer recurrence.

Symptoms and quality of life were evaluated using two patient-reported questionnaires – the National Cancer Institute’s Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) and European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ). Modified barium swallow studies assessed swallowing outcomes. Early findings suggest that reduced intensity chemoradiotherapy resulted in less acute toxicity and a decrease in side effects of mucositis (inflammation and of the mucous membranes lining the digestive tract), nausea, vomiting, swallowing difficulty and dryness of the mouth. Standard chemoradiotherapy regimens have reported feeding tube rates of up to 80 percent, approximately 10 percent of which were permanent. On the contrary, only 39 percent of patients in this study needed a feeding tube, none of which were permanent. Patients also reported that their swallowing function returned to almost normal, compared to baseline, pretreatment patient reports, and this was verified by the objective modified barium swallow studies, whereby patients’ swallowing difficulty is assessed using a fluoroscopic x-ray while they swallow various consistencies of food and liquids.
“Our study provides strong preliminary evidence that reduced intensity chemoradiotherapy may be as effective as standard dose chemoradiotherapy,” said lead study author Bhishamjit Chera, MD, associate professor of radiation oncology at University of North Carolina School of Medicine. “With further study, this regiment may become the new standard of care for carefully selected patients with HPV-associated squamous cell carcinoma of the oropharynx. The results so far are certainly encouraging, and with longer follow-ups, we hope to confirm less long-term side effects, as well.”

Additional data is needed, so at this time reduced intensity treatment should only be given if patients are enrolled in carefully controlled clinical trials, concluded Chera. He and his team are currently conducting a follow-up study among certain patients, in which biopsies and lymph node removal is only done if a 12-week post chemoradiotherapy PET scan is suspicious for persistent cancer is currently being conducted.

The abstract, “A Prospective Phase II Trial of Deintensified Chemoradiation Therapy for Low Risk HPV Associated Oropharyngeal Squamous Cell Carcinoma” will be presented in detail during a scientific session at ASTRO’s 57th Annual Meeting at 3:15 p.m. Central time on Sunday, October 18, 2015. To speak with Dr. Chera, please call Nancy Mayes in ASTRO’s Press Office at the Henry B. González Convention Center in San Antonio on October 18 – 21, 2015 at 210-258-8104 or 210-258-8105, or email press@astro.org.

ASTRO’s 57th Annual Meeting, to be held at the Henry B. González Convention Center in San Antonio, October 18-21, 2015, is the nation’s premier scientific meeting in radiation oncology. The 2015 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 D. Minsky, MD, FASTRO, a radiation oncologist specializing in gastrointestinal cancers, Professor of Radiation Oncology, and the Frank T. McGraw Memorial Chair at The University of Texas MD
Anderson Cancer Center, Houston, the theme of the 2015 Meeting is “Technology Meets Patient Care.” Dr. Minsky’s Presidential Symposium, “Multidisciplinary Management of Esophageal and Rectal Cancers,” will feature Leonard L. Gunderson, MD, MS, FASTRO, and Joel E. Tepper, MD, FASTRO, to highlight imaging, staging, genomics and data mining approaches, as well as the latest advances in esophageal and colorectal cancer treatment. ASTRO’s four-day scientific meeting includes presentation of more than 2,100 abstracts: five plenary papers, 351 oral presentations, 1,609 posters and 171 digital posters in more than 53 educational sessions and 26 scientific panels for 20 disease-site tracks. Three keynote speakers will address a range of topics including cancer biology in radiation oncology, the essential roles of a physician, and patient safety: Arul Chinnaiyan, MD, PhD, Professor and Director, Michigan Center for Translational Pathology; Francisco G. Cigarroa, MD, Past President and Chancellor, University of Texas; and Gerald B. Hickson, MD, Senior Vice President and Assistant Vice Chancellor, Vanderbilt University Medical Center.

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 who 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 three medical journals, International Journal of Radiation Oncology • Biology • Physics (www.redjournal.org), Practical Radiation Oncology (www.practicalradonc.org) and Advances in Radiation Oncology (www.advancesradonc.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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A Prospective Phase II Trial of Deintensified Chemoradiation Therapy for Low Risk HPV Associated Oropharyngeal Squamous Cell Carcinoma

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Purpose/Objective(s): We performed a prospective multi-institutional phase II study of a substantial decrease in concurrent chemoradiotherapy (CRT) intensity as primary treatment for favorable risk, HPV-associated oropharyngeal squamous cell carcinoma (OPSCC).

Materials/Methods: The major inclusion criteria were: 1) T0-T3, N0-N2c, M0, 2) HPV or p16 positive, and 3) minimal smoking history. Treatment was limited to 60 Gy intensity modulated radiotherapy with concurrent weekly intravenous cisplatinum (30 mg/m2). The primary study endpoint was pathologic complete response rate (pCR) based on required biopsy of the primary site and dissection of pretreatment positive lymph node regions, regardless of radiographic response. Power computations were performed for the null hypothesis that the pCR rate is 87% and N=40, resulting in a type I error of 14.2%. Secondary endpoint measures included physician reported toxicity (CTCAE), patient reported symptoms (PRO-CTCAE), quality of life (EORTC QLQ-C30 & H&N35), and penetration aspiration scale (PAS) scores for modified barium swallow studies.

Results: The study population is 43 patients. The pCR rate was 86% (37/43). All 6 non-pCR cases were limited to microscopic foci of residual cancer: 1 primary site, 5 nodal. All patients are alive with no evidence of disease (median follow-up 20.7 months, range 6-36 months). The incidence of CTCAE Grade 3/4 toxicity and PRO-CTCAE severe/very severe symptoms were: mucositis 34%/45%, pain 5%/48%, nausea 18%/52%, vomiting 5%/34%, dysphagia 39%/55%, and xerostomia 2%/75%. Grade 3/4 hematological toxicities were 11%. Mean pre and post CRT EORTC QOL scores were: Global 80/69 (lower worse), Pain 19/26 (higher worse), Swallowing 11/18, Coughing 17/22, Dry Mouth 16/64, and Sticky Saliva 6/49. 39% of patients required a feeding tube (none permanent) for a median of 15 weeks (5 - 22 weeks). There were no significant differences in PAS scores for thin, pureed, and solid foods before and after CRT.

Conclusion: Pathological CR rate with decreased intensity of therapy with 60 Gy of IMRT and weekly low-dose cisplatinum is very high in favorable risk OPSCC with evidence of decreased toxicity compared to standard therapies. (ClinicalTrials.gov, NCT01530997)