Daily humidification of the mouth and throat region during radiation therapy for head and neck cancer reduces mucositis and hospitalization, study finds

Scottsdale, Ariz., February 20, 2014—Patients who received daily humidification of the mouth and throat region beginning from day one of radiation therapy treatment spent nearly 50 percent fewer days in the hospital to manage their side effects, according to research presented today at the 2014 Multidisciplinary Head and Neck Cancer Symposium.

The study was conducted by the Trans Tasman Radiation Oncology Group and evaluated 210 head and neck cancer patients in New Zealand and Australia from June 2007 through June 2011. Patients in this Phase III trial were randomized to institutional standard of care (control arm) or humidification (HUM) using the Fisher & Paykel Healthcare MR880 humidifier. The humidified air is delivered through the nose via a plastic interface (mask-type apparatus) that can be worn by patients while sleeping or while sitting during the day.

Patients began HUM on day one of radiation therapy and continued until the ulceration their mouth and throat had resolved. On average, HUM patients spent 57 percent as many days in the hospital to manage side effects (control = 4.1 days vs. HUM = 2.3 days). The return of eating patterns to close to normal was also significantly higher at three months after radiotherapy in the group using humidifiers. (Nutritional Mode score at 20 weeks, a clinician-reported assessment of nutritional status, control = 4.8 vs. HUM = 5.23.)
Only 43 patients (42 percent of the patients in the HUM arm) met the defined benchmark of HUM compliance and were able to contribute to the per protocol (PP) analysis; the mean average use of humidification for these patients was 3.6 hours per day (range of use for all patients = 0-14 hours/day). In patients who met the HUM compliance benchmark, the area under the curve for CTCAE version 3.0 functional mucositis score (a clinician assessment of mucositis symptom burden for patients) was reduced (control = 8.63 vs. HUM PP = 6.74). The proportion of compliant HUM patients who never required a feeding tube was also increased (control = 0.73 vs. HUM PP = 0.85). There was also a trend for patients to report a reduction in symptom burden when using humidification but only in those patients compliant in using the humidifier.

“Mucositis (inflammation and ulceration of the mouth and throat) is a painful side effect of radiation therapy that can negatively affect patients’ quality of life. This study has provided efficacy signals consistent with a role for humidification in reducing symptom burden for patients during radiotherapy for head and neck cancer. Preventing or reducing hospitalizations may also mean it is cost effective. The rationale for using humidification is based on the fact that moisturizing wounds generally helps them heal faster,” said Andrew Macann, MBcHB, FRANZCR, lead author of the study and a radiation oncologist at Auckland City Hospital in Auckland, New Zealand. “These results are encouraging, particularly given the signals favouring humidification were seen across clinician-reported outcomes, patient-reported outcomes and independent data such as hospitalizations. Although patients in the study did not use the humidifiers as much as was hoped, we obtained feedback about why some patients did not like using the humidifier. Our next step is to work at increasing the proportion of patients who use the humidifier effectively.”

The abstract, “Domiciliary Humidification Reduces Symptom Burden and Hospital Admissions Associated With Mucositis During Radiotherapy For Head And Neck Cancer: Trans Tasman Radiation Oncology Group (TROG) 07.03 RadioHUM Randomised Phase III Trial Results,” will be presented in detail in the Plenary session at the 2014 Multidisciplinary Head and Neck Cancer Symposium at 12:30 p.m. Mountain time on Thursday, February 20, 2014. To speak with Dr. Macann, contact Michelle Kirkwood on February 20 – 21, 2014 in the ASTRO Press Office at the JW
Marriott Camelback Inn Resort and Spa in Scottsdale, Arizona at 480-596-7085 or email michellek@astro.org.

The 2014 Multidisciplinary Head and Neck Cancer Symposium is sponsored by the American Society for Radiation Oncology (ASTRO), the American Society of Clinical Oncology (ASCO) and the American Head & Neck Society (AHNS). The two-and-a-half day meeting includes interactive educational sessions focused on topics such as supportive care, directed therapy, new surgical and radio therapeutic techniques, as well as 12 oral abstract presentations of the current science of relevance to the head and neck cancer community. A total of 189 abstracts will be presented including 177 posters. Keynote speakers include Jennifer Grandis, MD, of the University of Pittsburgh, to present “The Molecular Road to Defining and Targeting High-risk Head and Neck Patients;” and Julia H. Rowland, PhD, of the National Cancer Institute, to present “Cancer Survivorship: Research Opportunities on the Path to Where We Want to Be.”

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2014 Multidisciplinary Head and Neck Cancer Symposium
News Briefing, Thursday, February 20, 2014, 7:00 a.m. Mountain time

Plenary Session: Thursday, February 20, 2014, 12:30 – 2:00 p.m. MT, Arizona Ballroom A-G, JW Marriott Camelback Inn Resort and Spa

2 Domiciliary Humidification Reduces Symptom Burden and Hospital Admissions Associated With Mucositis During Radiotherapy For Head And Neck Cancer: Trans Tasman Radiation Oncology Group (TROG) 07.03 RadioHUM Randomised Phase III Trial Results

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Background: To assess the impact of domiciliary based humidification (HUM) on symptom burden during radiotherapy (RT) for head and neck (H&N) cancer. Using a humidifier combines the principles of moist wound care and respiratory HUM.

Methods and Materials: From June 2007 through June 2011, 210 patients with H&N cancer receiving RT were randomized to either their institutional standard of care (control arm) or HUM using the Fisher & Paykel Healthcare MR880 humidifier. HUM commenced day 1 of RT and continued until Common Terminology Criteria Adverse Events (CTCAE) version 3.0 clinical mucositis (CMuc) ≤ 1. Acute toxicities, hospitalisations, and feeding tube events were recorded. The McMaster University H&N Radiotherapy Questionnaire (HNRQ) was used for patient reported evaluation of symptom burden. The primary endpoint was area under the curve (AUC) for CMuc ≥ 2.

Results: There was no significant difference in AUC CMuc ≥ 2 between the two arms [control 8.38 (7.19 - 9.57) HUM 8.25 (7.11 - 9.38); 95% CI; p 0.845]. Mean average HUM hours per day were 3.6 hours (range 0 - 14). Forty-three patients (42%) met a defined benchmark for HUM compliance and contributed to the per protocol (PP) analysis. In compliant HUM patients within the PP population, the AUC for CTCAE functional mucositis score (FMuc) ≥ 2 was reduced [control 8.63 (7.58 - 9.68); HUM 6.74 (5.40 - 8.08); p=0.009]. Weeks with FMuc ≥ 3 was just outside 5 % significance in the intention to treat (ITT) analysis [control 2.47 (1.83 - 3.10); HUM 1.07 (0.26 - 1.89); p 0.002]. HUM patients had significantly less days in hospital [mean total inpatient days ITT analysis: control 4.1 (2.7 - 6.0); HUM 2.3 (1.5 - 3.5); p=0.017] and the proportion requiring acute hospital admissions was reduced (PP analysis: control 0.55; HUM 0.31; p 0.013). The proportion never requiring a feeding tube was increased (PP analysis: control 0.73; HUM 0.85; p=0.04). Nutritional Mode, a clinician reported assessment of nutritional status, was higher in HUM patients at week 20 [ITT analysis: control 4.8 (4.47 - 5.13); HUM 5.23 (4.92 - 5.55); p 0.018]. HNRQ PP analysis estimates were in the direction favoring HUM with less symptom severity, although most time points did not reach significance.

Conclusions: TROG 07.03 has demonstrated efficacy signals consistent with a role for HUM in reducing symptom burden from mucositis, but the influence of HUM compliance on the results moderates recommendations regarding effectiveness.

Author Disclosure Block: A. Macann: None. S. Porceddu: None. C. Milross: None. T. Fua: None. M. Penniment: None. M. King: None. M. Bell: None. C. Fraser-Browne: None. V. Thomson: None. H. Hockey: None.