Background: Yangzheng Xiaoji (YZXJ) is a Chinese medicine formulation made of 16 herbs and used in patients with solid cancers. The aim of this randomized, double-blind and placebo-controlled multi-center trial (YANG-1, ClinicalTrials.gov registration No. NCT02195453) is to evaluate the impact of Yangzheng Xiaoji capsule on the quality of life (QoL) and treatment-related side effects in patients with advanced non-small cell lung cancer (NSCLC) receiving chemotherapy. Method: Patients with advanced NSCLC and with Eastern Cooperative Oncology Group performance status 0 to 1, who receive first-line chemotherapy (gemcitabine or pemetrexed and cisplatin), were randomized (1:1) to Yangzheng Xiaoji (YZXJ) or placebo combined with chemotherapy. The primary endpoint was QoL (Functional Assessment of Cancer Therapy-Lung (FACT-L) and Lung Cancer Symptom Scale (LCSS)) after two or four cycles of chemotherapy. The second endpoints included overall response rate, progression free survival and toxicity. Result: Between 10/2014 and 4/2017, the trial enrolled and randomized 504 patients from 25 centers in China. 397 patients received at least two cycles of chemotherapy and were included for final analysis. Baseline characteristics, including FACT-L and LCSS scores, were well balanced between two groups. The mean FACT-L scores were significantly changed in both groups from the baseline to that after chemotherapy (97.58 increase to 100.89 in YZXJ/chemotherapy arm, P<0.001; 93.83 decrease to 97.93 in placebo arm, P<0.001). The mean score of LCSS from baseline was significantly changed in *YZXI*/chemotherapy groups (25.84 decrease to 22.31, P < 0.001), but there was no statistical difference in the placebo group(25.59 vs. 26.45, P=0.136). The YZXJ/ chemotherapy arm had a better QoL than the placebo/chemotherapy arm (FACT-L, 3.30 vs. -4.09; P<0.001) as well as improved lung cancer symptoms compared with placebo (LCSS, -3.53 vs. -0.86; P < 0.001). There was no statistical difference in chemotherapy completion rate, ORR and PFS between two groups. The most common adverse events were bone marrow toxicity (70.92% vs. 67.59%) and gastrointestinal reaction (34.66% vs. 63.24%) (YZXJ vs. Placebo, P=0.441 and P<0.001, respectively). The rate of fatigue was significantly lower in YZXJ group than placebo group (4.38% vs. 30.04%, P<0.001). Conclusion: For patients with advanced NSCLC who received platinum-based chemotherapy, Yangzheng Xiaoji Capsule significantly improved the quality of life and symptoms, especially fatigue and gastrointestinal reaction. Keywords: Yangzheng Xiaoji (YZXJ), chemotherapy, Advanced Non-Small Cell Lung Cancer

MA02.07

Aprepitant for Cough Suppression in Advanced Lung Cancer: A Randomized Trial

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Background: Cough is a distressing symptom in patients with lung cancer. Effective management of cough leads to improvement in quality of life (QoL) and optimal palliative care. Aprepitant, a centrally acting neurokinin-1 inhibitor, has been shown in a pilot study to significantly decrease the cough frequency. **Method:** A randomized open-label study in patients with advanced lung cancer with cough for over 2 weeks despite therapy with a cough suppressant, with an ECOG performance status 0 to 2. Patients were randomized 1: 1 to Arm A: aprepitant 125 mg orally on day 1, followed by 80 mg orally on days 2 to 7 along with physician's choice of antitussive therapy. Patients on

Arm B received physician's choice of antitussive therapy. Patients were evaluated at baseline and then on days 3, 7, 9 and 12. Primary efficacy endpoint was subjective improvement in cough, measured with the Visual Analog Scale (VAS) and the Manchester Cough in Lung Cancer Scale (MCLCS). Secondary endpoints included toxicity and QoL, measured by the EORTC QLQ-C30 and LC13. The trial was approved by the` institutional IEC and registered with (CTRI/2017/ 05/008691). Result: Between June 2017 and June 2018, 128 patients were randomized: 64 to each arm. The median age was 53 yrs, 65% male, 64% never-smokers, 82% had adenocarcinoma. 88% had Stage IV disease; 80% had PS 1 and 20% PS 2. The median duration of cough was 90 days. VAS scores at baseline and day 9 was 67.93, 38.50 in Arm A and 63.15, 48.57 Arm B , with $p{<}0.001$ and the MCLCS scores at baseline and day 9 was 30.03, 22.32 in Arm A and 27.53, 23.80 Arm B , with p<0.001. Overall, there was no significant difference in the QoL scores in patients in the two arms, however there was a significant improvement in the cough-specific QoL domain in the patients on the aprepitant arm, p=0.017. There was no increase in the grade 3 and higher adverse events in the patients on the aprepitant arm. Conclusion: Aprepitant led to a significant improvement in cough in patients with advanced lung cancer, with no increase in severe side-effects. Aprepitant should be considered as one of the treatment options for cough in lung cancer patients.

MA02.08

The Effect of Nabilone on Appetite, Nutritional Status, and Quality of Life in Lung Cancer Patients: A Randomized, Double-Blind Clinical Trial

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Background: Over one half of the patients diagnosed with advanced lung cancer experience anorexia. In addition to its high incidence, cancer-induced anorexia promotes the development of the anorexia-cachexia syndrome, which is related to poor clinical outcomes. Recently, drugs derived from cannabinoids, such as Nabilone, have been recognized for their appetite improvement properties; however, clinical trials to support their use in cancer patients are necessary. Method: This is a randomized, double-blind, placebo-controlled clinical trial to assess the effect of Nabilone vs. placebo on the appetite, nutritional status, and quality of life in patients diagnosed with advanced Non-small cell lung cancer (NSCLC) (NCT02802540). Result: A total of 65 patients from the outpatient clinic at the National Institute of Cancer (INCan) were assessed for eligibility and 47 were randomized to receive Nabilone (0.5 mg/2 weeks followed by 1.0 mg/6 weeks) or placebo. After 8 weeks of treatment, patients who received Nabilone increased their energy intake (342-kcal) and had a significantly improvements in Quality of life parameters. Conclusion: Nabilodne is an adequate and safe therapeutic option to aid in the treatment of patients diagnosed with anorexia. Larger trials are necessary in order to draw robust conclusions in regard to its efficacy in lung cancer patients. Keywords: anorexia, orexigenic agent, lung cancer

