

# 6<sup>th</sup> World Pharmacists and Clinical Pharmacy Annual Congress

May 22-23, 2017 Chicago, USA

## Low-dose oral acetylcysteine in the attenuation of cisplatin-induced nephrotoxicity: A randomized double-blind placebo-controlled pilot trial in patients with head and neck cancer

Marilia B Visacri, Julia C F Quintanilha, Lais S Amaral, Vanessa M Sousa, Carmen S P Lima and Patricia Moriel  
University of Campinas, Brazil

**Statement of the Problem:** Cisplatin chemotherapy induces oxidative stress and therefore has consequent toxicities. The main dose-limiting side effect of cisplatin is nephrotoxicity. The protective antioxidant role of acetylcysteine (NAC) on nephrotoxicity due to cisplatin has been reported in experimental models; however, its efficacy in patients has not been elucidated. The aim of this study was to evaluate the possible protective effect of low-dose oral NAC on cisplatin-induced nephrotoxicity in patients with head and neck cancer.

**Methodology & Theoretical Orientation:** This is a randomized double-blind placebo-controlled pilot trial conducted with 57 patients undergoing treatment with at least one of the three cycles of high-dose cisplatin chemotherapy, concomitant to radiotherapy. Patients were randomly assigned and were given: (1) NAC syrup, 600 mg orally once a day at night for 7 consecutive days (two days before the chemotherapy, on the day of chemotherapy and 4 days after chemotherapy), n=28; or (2) Placebo, administered similarly to NAC, n=29. Plasma levels of creatinine were monitored to assess nephrotoxicity. Creatinine clearance was estimated using the Cockcroft-Gault formula. Severity was classified by Common Toxicity Criteria for Adverse Events (version 4, grade 0 to 4).

**Findings:** Patients from both groups had similar demographics and clinical characteristics ( $p>0.05$ ). Throughout the treatment, elevated creatinine was observed in 55.2% of patients in placebo group (grade 1+2: 34.5%; grade 3: 20.7%) and 64.3% in NAC group (grade 1+2: 46.4%; grade 3: 17.9%) [Chi-square test,  $p=0.6517$ ]. Moreover, reduced creatinine clearance was observed in 96.6% of patients in placebo group (grade 1+2: 75.9%; grade 3+4: 20.7%) and 96.4% in NAC group (grade 1+2: 82.1%; grade 3+4: 14.3%) [Fisher's exact test,  $p=0.8620$ ].

**Conclusion & Significance:** Low-dose oral NAC did not attenuate cisplatin-induced nephrotoxicity. Further studies should be conducted to test other oral doses of NAC

### Biography

Marilia B Visacri has received her Bachelor's degree in Pharmacy from the University of Campinas, Campinas, Brazil, in 2011 and MSc degree in Medical Sciences from the same university in 2013. She is currently pursuing her PhD degree in Sciences at School of Medical Sciences, University of Campinas, Brazil. Her research interests include clinical pharmacy, pharmaceutical care, adverse drug reactions, oncology, oxidative stress biomarkers and biomarkers for adverse events

mariberlofa@gmail.com

### Notes: