

## Prevention of cisplatin nephrotoxicity (CN) in head and neck cancer patients receiving concurrent chemoradiation (CCRT) by adding oral rehydration solution (ORS) to short hydration regimen: a randomized open-label controlled trial.

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**Background:** CN remains a frequent occurrence despite receiving standard fluid hydration, particularly for head and neck cancer patients undergoing CCRT. We aimed to investigate whether adding ORS to short hydration regimen can reduce CN.

**Methods:** We conducted a randomized open-label controlled trial in patients with head and neck cancer receiving CCRT with 3-weekly cisplatin ( $\geq 50$  mg/m<sup>2</sup>). Eligible patients were randomly assigned to receive short hydration regimen (2000 mL of normal saline on day 1) alone or in combination with 2000 mL of ORS on days -1, 2 and 3 of each cycle. The primary end point was the incidence of  $\geq$  gr 1 creatinine (Cr) elevation on day 8. Key secondary end points were Cr elevation on day 90, and safety. The planned sample size was 160 (80 patients each arm).

**Results:** Thirty-nine patients in ORS group and 41 patients in control group (50% of planned sample size) were enrolled. Baseline characteristics were balanced between the two groups, except more patients in ORS group underwent surgery (30.8% vs. 22%), and had less feeding tube prophylaxis (79.5% vs. 85.4%), although there were not statistically significant. The mean dose of cisplatin on day 1 was significantly higher in ORS group (90 mg/m<sup>2</sup> vs. 84.4 mg/m<sup>2</sup>,  $p=0.01$ ). There were no difference of volume of total fluid intake and toxicities between the two groups. The incidence of  $\geq$  gr 1 creatinine (Cr) elevation on day 8 was 87.2% in the ORS group, as compared with 90.2% in the control group ( $p=0.734$ ). Less percentage of patients in ORS group developed  $\geq$  gr 1 Cr elevation on the subsequent visits; 66.7% vs. 73.2% on day 15, 66.7% vs. 70.7% on day 22, and 66.7% vs. 73.3% on day 90, although there were not statistically significant.

**Conclusions:** Although our interim analysis showed no significant difference of CN between the groups, there was a trend that addition of ORS might prevent acute and chronic kidney injury secondary to cisplatin. The completed enrollment is warranted to confirm this early findings.