

## Weekly Cisplatin and Docetaxel plus Concomitant Boost Concurrently with Radiation Therapy in the Treatment of Locally Advanced Head and Neck Cancer: Phase II Trial

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### **Abstract**

**Purpose:** The aim of this phase II clinical study is to investigate the feasibility of combining concomitant boost radiation therapy regimen (CBRT) with weekly cisplatin and docetaxel and to assess, toxicity and survival in patients with locally advanced squamous cell carcinoma of the head and neck (SCCHN).

**Patients and Methods:** Between January 2007 to January 2009, 36 patients diagnosed with locally advanced, non-metastatic (stage III–IV) Head and neck squamous cell carcinoma (HNSCC) at Tanta and Menofia University Hospitals were recruited. Radiotherapy dose was 72 Gy in 42 fractions over 6 weeks delivered for gross disease, and uninvolved nodes received 54 Gy in 6 weeks. Chemotherapy consisted of Cisplatin 20 mg/m<sup>2</sup> IV and docetaxel 15 mg /m<sup>2</sup> I.V. given concurrently with radiotherapy during working week-day time. Both drugs administered weekly (week 1 through 4).

**Results:** Thirty-six patients were enrolled for response, survival and toxicity. Primary sites were: larynx 19, hypopharynx 9, and oropharynx 8. All patients had T3/T4 disease (58.3% & 41.7% respectively), and only 22.2% of patients had N0 disease. Overall response was observed in 32 patients (88.9%) with 95% confidence interval equal 74.7 to 95.6. Four patients (11.1%) developed progressive disease (95% CI equal 4.58 to 25.67). The 2-year overall survival and progression-free survival rates were, 68.9% (95% CI, 52.6 to 81.6 %) and 53.9% (95% CI, 38.04 to 69.01%), respectively. The 2-year loco-regional control rate was 62.4% (95% CI, 46.0 to 76.2 %). Incidence of grade III was mucositis in 77.8%, acute skin toxicity in 22.2% and neutropenia in only 11.1%

**Conclusions:** Concomitant boost radiation therapy plus concurrent weekly cisplatin and docetaxel is a feasible schedule in patients with locally advanced head and neck carcinoma, with acceptable toxicity. The survival data in this study was comparable with other trials using CBRT plus concurrent single agent cisplatin either weekly or every three weeks. A randomized phase III study is needed to compare this regimen with bolus cisplatin either weekly or every three weeks