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Phase II trial: concurrent radio-chemotherapy with weekly docetaxel for advanced squamous cell carcinoma of head and neck

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Abstract *Introduction:* Standard fractionation radiation therapy (RT) combined with concomitant chemotherapy (CT) based on cisplatin schemes is actually the standard treatment for locally advanced non-resectable squamous cell carcinoma of head and neck (SCCHN). The appearance of taxoids has introduced a new kind of treatment with high antitumoral power. The aim of this study is to add more information about the role of this new approach. *Materials and methods:* Twenty-six patients with locally advanced non-resectable SCCHN were recruited at six institutions in Spain, between January 2001 and January 2003. Docetaxel was administered weekly, for 6 weeks, concurrently with RT. *Results:* The mean total delivered dose of RT was 70'2 Gy (range 64–74 Gy). The median and mean duration of time were 63 days and 61 days (range 49–103 days) respectively. After a median time control of 19 months (range 3.3–42.2 months), the response rate was 83.4%. The median time to local progression was 16.4 months (95% confidence interval [CI]=4.4–28.4 months). The median survival time was 26.9 months, with one- and two-year overall survival of 66.9% (95% CI=48.1–85.7%) and 57.5% (95% CI=37.3–77.7%) respectively. The median duration time response was 15.1 months (95% CI=3.7–26.5 months). The median time until treatment failure was 9.4 months (95% CI=4.7–14.1). Incidence of grade III–IV mucositis was 88%, neutropenia 72% and skin toxicity 92% (24% grade III–IV). The incidence of severe late toxicity (grade III and IV) due to RT/CT was 31.4%. *Conclusions:* Although therapeutics results are equivalent to cisplatin schemes of concurrent CT-RT, mucositis and cutaneous toxicity registered in this trial must be considered as limiting factors to application of this new approach.

Key words Squamous cell carcinoma of head and neck • Docetaxel • Treatment • Toxicity

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