Cisplatin plus fluorouracil (5-FU) is widely accepted as neoadjuvant and adjuvant chemotherapy in the treatment of head and neck squamous cell carcinoma; UFT is also an active agent against this disease. In the first retrospective study, we examined the efficacy of UFT as adjuvant chemotherapy in patients with maxillary cancer.

**Introduction**

UFT (uracil and tegafur), an active agent against advanced head and neck squamous cell carcinoma (HNSCC), is widely used in Japan.[1] Its efficacy for adjuvant chemotherapy has been proved in randomized studies.[2] In the first of two retrospective studies, we examined the efficacy of UFT as adjuvant chemotherapy in patients with maxillary cancer. The next study developed the UFT and carboplatin (Paraplatin) regimen as a modification of cisplatin (Platinol) plus fluorouracil (5-FU) to determine its activity and evaluate toxicity in advanced HNSCC patients.[3]

**Study 1: Adjuvant Chemotherapy With UFT**

This study included 48 patients with maxillary sinus squamous cell carcinoma who proved disease-free after definitive treatment with surgery or chemoradiotherapy. UFT (200 mg/m²/day) was continuously administered for more than 1 year. In all, 15 patients were successfully administered UFT; nine patients did not complete the schedule due to toxicity, and 24 did not receive UFT (Table 1). Survival rates were retrospectively compared between patients treated with and without UFT.

**Results**

The 5-year survival rate in 39 evaluable patients was 41.5% in T3 patients and 20.2% in T4 patients (Figure 1). The 5-year survival rate in patients treated with UFT or without UFT was 76.6% and 22.6%, respectively. This indicates a significantly higher survival in the UFT patients ($P = .001$) (Figure 2). Comparison was made in 23 patients with or without UFT and five discontinued patients at T3. The 5-year survival rate was 71.4% in the UFT group, 23.8% in the group without UFT, and 40.0% in the UFT-discontinued group. These results indicate a favorable prognosis for the UFT group compared with the group without UFT ($P = .033$) and the UFT-discontinued group ($P = .731$) (Figure 3).

**Study 2: UFT With Carboplatin**

Patients with evaluable and unresectable HNSCC were enrolled in this study (Table 1). All the patients had normal bone marrow, renal, pulmonary functions and performance status of 0 or 1 (ECOG). UFT (400 mg/day) was administered from day 1 to day 14 and from day 28 to day 42. Carboplatin (350 mg/m²) was administered at day 7 and day 35.

**Results**

Two complete responses and 15 partial responses were observed, for an overall response rate of 53.1% (95% confidence interval, 35.8% to 70.4%). The antitumor efficacy in terms of lesion site is shown in Table 2. Toxicities greater than grade 3 were rare. Two patients experienced grade 3 leukopenia; one patient, grade 4 anemia; two patients, grade 3 thrombocytopenia. There were no grade 3 or higher gastrointestinal tract toxicities, fever, or stomatitis (Table 3).

**Conclusions**

Adjuvant chemotherapy with UFT achieved longer survival duration for patients with maxillary cancer.
compared with patients not receiving UFT. UFT plus carboplatin was proved to have efficacy for advanced HNSCC with mild toxicity. This regimen will be applied as adjuvant chemotherapy in the outpatient setting. To avoid grade 3 and 4 hematologic toxicity with this regimen, a dose-finding study for carboplatin is required.

**References:**


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