667 PUBLICATION

External beam radiotherapy in the treatment of T3 vocal cord tumors

M. Marques[1], C. Castro[1], M.A. Costa[1], E. Monteiro[2], T. Fernandes[1]. [1]*Instituto Português de Oncologia, Radiotherapy, Porto;* [2]*Instituto Português de Oncologia, Otolaryngology, Porto, Portugal*

Purpose: The mainstay of treatment in most centres for extensive T3 vocal cord tumors is total laryngectomy, usually followed by radiotherapy (RT). Radical RT is prescribed for the patient that refuses surgery (SUR), is medically unsuitable for a major operation or before deciding on RT alone or total laryngectomy. The authors analysed retrospectively the patients with the diagnosis of T3 vocal cord tumors treated at the Department of Radiotherapy – Instituto Português de Oncologia-Porto.

Methods: Sixty patients with the diagnosis of T3 vocal cord tumors treated in our Department between January 1975 and December 1996 were reviewed. They were divided in 3 groups, according to the treatment: RT (group 1); SUR + RT (group 2) and RT + SUR (group 3). Patient's sex, age, smoking and drinking habits, clinical presentation, histology, stage, treatments done, their results and patterns of recurrence were analysed, as well as laryngeal function, when preserved. The disease-free survival (DFS) and overall survival (OS) were calculated in each group by the "Life-Table" method; differences between results were analysed with the generalised Wilcoxon test. Statistical significance was defined as $p < 0.05$.

Results: Fifty-eight were male and 2 female. The median age at diagnosis was 64 years (range 34–82). The vast majority presented with hoarseness and had squamous cell carcinomas. Fifty five patients were T3N0M0 and five T3N1M0. All the patients received RT, which was performed as the sole treatment in 38.3% of the cases, post-operatively in 28.3% and with a pre-operative intent in 33.3%. The DFS was 65.6% and the OS 69.9%. In group 1, the OS at 5 years was 53.4%, being 93.3% and 68.3% in groups 2 and 3, respectively. The difference in OS between groups 1 and 2 and 2 and 3 was statistically significant ($p = 0.008$ and $p = 0.03$, respectively); between groups 1 and 3 the differences in OS were not statistically significant ($p = 0.1$).

Discussion: In the present study, the group treated with SUR + RT presented the best results in OS and DFS. However, RT as a sole treatment had a 5 year,s OS of 53.4% which demonstrates its value in the situations described before. Some patients in this category are cured and maintain an useful voice, fact that is very important if we remember that we are leading with advanced lesions.

668 PUBLICATION

Second primary tumors in patients with early glottic cancer

M. Lobão[1], L. Alves[1], M.A. Costa[1], T. Fernandes[1]. [1]*Instituto Português de Oncologia, Radiotherapy, Porto, Portugal*

Purpose: The development of second primary tumors (SPTs) in patients who have had their first tumor treated successfully, represents a serious limitation of current therapeutic strategies for head and neck cancers. Early-stage glottic cancer represents a situation in the head and neck region, where the local therapy is expected to result in 5-year control up to 95%. However, it is generally agreed that the SPTs in this region are not treatment-related, but are related to the common etiological risk factors. The authors analysed retrospectively the patients with the diagnosis of SPTs in patients treated successfully for early glottic tumors, at the Department of Radiotherapy from the Instituto Português de Oncologia-Porto.

Methods: Thirteen patients with the diagnosis of SPTs after successful treatment for T1/T2 vocal cord tumors in our Department between January 1976 and December 1996 (in a total of 121) were reviewed. We analysed the distribution by sex and age, smoking history, alcohol consumption, the first clinical symptom, localisation, histology and histological grade of the tumor, laryngeal function, overall and disease-free survivals, the incidence, time to development of the SPTs, treatments done and results.

Results: All the patients were male. The median age at diagnosis was 60.7 years (range 48–75). The vast majority presented with hoarseness and had squamous cell carcinomas. Nine patients were T1N0M0 and four T2N0M0. All the patients received RT, as the sole treatment to the vocal cord tumor. The median time to develop the SPTs was 6.3 years (range 3–12). The locations of the SPTs were: lung (5); bladder (3); sigmoid (2); esophagus (1); stomach (1) and choroid melanoma (1). The amount of smoking and alcohol consumption were the two significant prognostic factors for the development of SPTs ($p = 0.005$). Only five patients (38.5%) are alive and only one without evidence of disease (choroid melanoma).

Discussion: Development of SPTs becomes an issue when the primary tumor could be effectively treated and patients are expected to live long enough. The development of malignancy within the upper aerodigestive tract and lungs conforms well to the model of multistep carcinogenesis involving the steps of initiation, promotion and progression. In the present study, all the patients were free from disease concerning the primary tumor and with a normal laryngeal function. SPTs were the leading cause of death in these patients. Until better genetic markers are developed, chemoprevention offers the best strategy to reduce the incidence in high-risk patients.

669 PUBLICATION

Phase II study with IL-2 combined with vincristine, bleomycin, and methotrexate (VBM) in recurrent head and neck carcinomas

G. Gambaro, P. Bagnasacco, A. Ballarè, L. Turri, A. Prino, G. Oro, M. Krengli. *Dept. of Radiotherapy, University of East Piedmont, Novara, Italy*

Purpose: Several studies show that IL-2 can enhance antitumoral activity of many cytotoxic drugs with possible additive or synergistic effect. The purpose of this study is to assess the feasibility, efficacy and toxicity of IL-2 combined with VBM chemotherapy in patients with recurrent head and neck carcinomas.

Material and Methods: Twenty-six pts with recurrent previously treated head and neck carcinomas were enrolled. The regimen included four cycles of VBM (VCR 1 mg, day 1, BLM 15 mg, 6 and 24 hours after VCR, MTX 20 mg/m^2 day 3) and IL-2 6.000.000 IU sc days 4–7, given weekly. Patients with response received further 4 cycles. Twenty-two patients were evaluable: 14 with T, 2 with N, 5 with T + N, and 1 with T + M (bone) relapses. Tumor sites were: oral cavity in 10, larynx in 5, oropharynx in 2, hypopharynx in 1, nasopharynx in 1, ethmoid in 1, salivary gland in 1, and ear in 1 case.

Results: Overall response was observed in 9/22 (41%) pts: 6/22 (27.4%) CR, 3/22 and (13.6%) PR. No response or progression in 13 pts. The time to progression after CR-PR ranged from 2 to 14 months (median 4 months); the overall survival ranged from 3 to 14 months (median 7 months). Toxicity (WHO scale) resulted in grade I–II in 21 pts; only 1 pt fall in grade IV.

Conclusion: This study suggests that IL2 combined with VBM chemotherapy is a quite effective regimen in recurrent head and neck carcinomas. The treatment schedule is feasible and the toxicity is acceptable.

670 PUBLICATION

A phase II study of vinorelbine (VRL), cisplatin (CDDP) and 5-Fluorouracil (FU) in patients (PTS) with locally advanced recurrent, and/or metastatic squamous cell carcinoma of the head and neck (SCCHN)

V. Guillem, M.A. Muñoz, R. Yaya, V. Soriano, M.A. Climent, C. Gaspar. *Instituto Valenciano de Oncologia, Valencia, Spain*

As a single agent or in combination with CDDP or FU, vinorelbine has been demonstrated to be active against SCCHN (Gebbia, 1999). This trial was conducted in order to confirm previous data in terms of efficacy and tolerance with more intensive dose of CDDP.

Methods: From 05/94 to 02/97, 37 patients with histologically confirmed metastatic, locally recurrent or surgically unresectable SCCHN previously untreated by chemotherapy have been accrued. Treatment consisted of vinorelbine 20 mg/m^2 on day 1 and 8, 5-FU: 650 mg/m^2 per day, in continuous infusion over day 1 to 4 and CDDP: 100 mg/m^2 on day 1 in a 21 day-schedule.

Results: Most of pts had oral cavity, larynx, or oropharynx carcinoma (95%). 19 pts were recurrent or metastatic after a prior treatment (surgery and/or radiation). 13 pts had locally advanced disease or stage IV. Median age 59 y (39–74). WHO PS 0–1: 97%. 127 cycles were administered, mean of 3.5 courses (range 1–6). There was 57% ORR (CR: 16%), 28% of pts underwent surgery + radiation therapy and 69% radiotherapy after downstaging. The median overall survival was 10 m (1–41 + m) and the 1 y survival was 43%. WHO G3-4 N/V occurred in 8.1% of treated pts (3.1% of cycles) despite antiemetic treatment. G2-3 stomatatis was observed in only 3.1% of cycles. Severe neutropenia was experienced by 41% of pts, with 3 septic deaths.

Conclusion: This regimen is highly active in the management of advanced or metastatic SCCHN but needs to be re-scheduled in order to improve tolerability.