

Exemestane in Early Breast Cancer

In the January 22 issue of the *Lancet*, van de Velde and colleagues reported the results of the TEAM (Tamoxifen Exemestane Adjuvant Multinational) trial, which compared the long-term effects of exemestane monotherapy with tamoxifen followed by exemestane (sequential treatment) in postmenopausal women with hormone receptor-positive breast cancer. This phase III trial was conducted in hospitals throughout 9 countries. Patients were randomly assigned to receive open-label exemestane (25 mg) alone or following tamoxifen (20 mg) orally once per day for 5 years. The intention-to-treat analysis included 4,868 patients in the sequential group and 4,898 patients in the exemestane monotherapy group. The primary endpoint of disease-free survival at 5 years was 85% in the sequential group and 86% in the exemestane alone group (hazard ratio [HR], 0.97; 95% confidence interval [CI], 0.88–1.08; $P=.6$). The sequential treatment group had higher incidences of gynecologic symptoms (20% vs 11%), venous thrombosis (2% vs 1%), and endometrial abnormalities (4% vs <1%). In the group taking exemestane alone, there was a higher incidence of musculoskeletal adverse events (50% vs 44%), hypertension (6% vs 5%), and hyperlipidemia (5% vs 3%). The study investigators concluded that both exemestane monotherapy and sequential treatment might be considered appropriate options for postmenopausal women with hormone receptor-positive early breast cancer.

Docetaxel Added to Cisplatin and Fluorouracil Improves Survival in Squamous Cell Carcinoma of the Head and Neck

Long-term study results of TAX 324 (A Randomized Phase III Multicenter Trial of Neoadjuvant Docetaxel [Taxotere] Plus Cisplatin and 5-Fluorouracil [TPF] Versus Neoadjuvant Cisplatin Plus 5-Fluorouracil Followed by Concomitant Chemoradiotherapy to Improve the Overall Survival and Progression Free Survival in Patients With Locally Advanced Squamous Cell Carcinoma of the Head and Neck) were published in the February issue of the *Lancet Oncology*. The addition of docetaxel to standard induction chemotherapy with cisplatin and fluorouracil (PF) significantly improved the long-term survival of patients with stage III or IV locally advanced squamous cell carcinoma of the head and neck, reducing the risk of death by 26% over 6 years. In this open-label, phase III trial, 501 patients were randomized to receive either 3 cycles of docetaxel, cisplatin, and fluorouracil (TPF) or 3 cycles of PF. All patients then received 7 weeks of chemoradiotherapy with weekly carboplatin. To determine whether the survival benefits of the TPF regimen measured at a minimum follow-up of 2 years endured with

time, Lorch and coworkers performed an analysis of data gathered retrospectively from the TAX 324 patients' medical records as of December 1, 2008. The median follow-up was 72.2 months (95% CI, 68.8–75.5). The estimated survival at 5 years was 52% in the TPF group and 42% in the PF group. The median overall survival in the TPF group was 70.6 months (95% CI, 49.0–89.0) compared with 34.8 months (95% CI, 22.6–48.0) in the PF group ($P=.014$). Progression-free survival (PFS) was significantly longer for patients receiving TPF than for those receiving PF (median, 38.1 vs 13.2 months). Gastric feeding tube dependence and rates of tracheostomies did not differ significantly between treatment groups. The researchers concluded that in locally advanced head and neck cancer patients, induction chemotherapy with TPF had a greater long-term survival benefit compared with PF.

Rituximab Maintenance Improves PFS in Follicular Lymphoma

The randomized, open-label, phase III PRIMA (Primary Maintenance and Rituximab) study assessed the potential benefit of 2 years of rituximab (Rituxan, Genentech) maintenance after first-line treatment in patients with follicular lymphoma receiving a rituximab plus chemotherapy regimen. Results were reported in the January 1 issue of the *Lancet* by Salles and associates. The study was conducted in 223 centers in 25 countries. Eligible patients had previously untreated follicular lymphoma that required systemic therapy. After initial induction therapy with cyclophosphamide, vincristine, and prednisone (CVP); cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP); or fludarabine, cyclophosphamide, and mitoxantrone (FCM), 1,019 patients achieved a complete or partial response. There were 505 patients assigned to 2 years of rituximab maintenance therapy and 513 patients assigned to observation; 1 death occurred during randomization. The rituximab group experienced a PFS rate of 74.9% (95% CI, 70.9–78.9) compared with 57.6% (95% CI, 53.2–62.0) in the observation group (HR, 0.55; 95% CI, 0.44–0.68). Complete or unconfirmed complete response 2 years after randomization was observed in 361 patients (71.5%) in the rituximab maintenance group and 268 (52.2%) in the observation group ($P=.0001$). There was no significant difference in overall survival between the 2 groups (HR, 0.87; 95% CI, 0.51–1.47). The frequency of grade 3/4 adverse events was 24% in the rituximab maintenance group and 17% in the observation group (risk ratio [RR], 1.46; 95% CI, 1.14–1.87). The most common adverse events were infections (grade 2–4), which occurred in 39% of the rituximab maintenance group and 24% of the observation group (RR, 1.62; 95% CI, 1.35–1.96; $P<.0001$).