during the first three cycles of CT was significantly more frequent in older premenopausal BC pts, than in younger ones. Finally, amenorrhea was permanent, according to the 4 age groups, in 3%, 3.5%, 51% and 73% pts, respectively, while the frequency of temporary amenorrhea decreased with the age from 15% to 9.8%. The number of CT cycles also significantly influenced the frequency of amenorrhea: it occurred in only 22.5% pts who received less than 6 cycles of CT, and in 53.7% of those who received 6 or more than 6 CT cycles. The later result was probably additionally influenced by the cumulative dose of the anthracycline.

In conclusion, amenorrhea induced by anthracycline regimens seems to be less frequent than in non-anthracycline CMF-based regimens. It is rather rare in very young women. These finding could be important in a multiple clinical aspects: from the adjuvant endocrine treatment planning in premenopausal endocrine-responsive BC pts to the prediction of the loss of fertility in BC survivors.

295 POSTER HIGHLIGHT

Lamivudine for the prevention of hepatitis B virus reactivation in hbsag seropositive cancer patients undergoing cytotoxic chemotherapy

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Background: Breast cancer is a rapidly increasing problem in many developing countries and cytotoxic chemotherapy is now an integral part of its management. In several developing countries, the carriage of hepatitis B virus (HBV) in cancer patients may be as high as 12% and such patients are at risk of developing HBV reactivation during chemotherapy, which is a well-described complication resulting in varying degrees of liver damage that may lead to death. In this prospective study, breast cancer patients with chronic HBV infection received the antiviral agent lamivudine prior to chemotherapy, the objectives were to assess the efficacy of lamivudine in reducing the incidence of HBV reactivation, and diminishing morbidity and mortality during chemotherapy.

Methods: The study group consisted of 27 patients who were treated with lamivudine prior to and until 8 weeks after discontinuing chemotherapy (the 'prophylactic lamivudine' group). They were compared with historical controls which consisted of 41 consecutive patients who underwent chemotherapy without prophylactic lamivudine. The outcomes, in terms of the incidence of HBV reactivation and clinical consequences, were compared.

Results: The 2 groups were comparable in most baseline-characteristics, although in the prophylactic lamivudine group, there were significantly more patients receiving anthracyclines (96% vs 51% in the controls, p<0.001). In the prophylactic lamivudine group, there was significantly less HBV reactivation (7% vs 41% in the controls, p=0.003), fewer incidences of hepatitis (11% vs 66%%, p<0.001) that were less severe (7% vs 15%, p=0.117), and less disruption of chemotherapy (26% vs 51%, p=0.02). There was no associated mortality in both groups.

Conclusions: Prophylactic lamivudine significantly reduced the incidence and morbidity of HBV reactivation in breast cancer patients undergoing chemotherapy.

296 POSTER HIGHLIGHT

Long-term safety of zoledronic acid for the treatment of patients with breast cancer and bone metastases

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Background: Zoledronic acid has demonstrated clinical benefit superior to that of pamidronate for the treatment of bone metastases in patients with breast cancer. Moreover, zoledronic acid can be administered via a more convenient 15-minute infusion. However, concerns have been raised regarding the renal safety profile of zoledronic acid. Herein, the renal safety profile of 4 mg zoledronic acid (via 15-minute infusion) is compared with that of 90 mg pamidronate (via 2-hour infusion).

Materials and methods: Patients were randomized to receive zoledronic acid or pamidronate every 3–4 weeks for up to 25 months in a multicenter, phase III trial. Data presented are from the stratified subset of 766 patients with breast cancer. A notable increase in serum creatinine was defined as an increase of ⩾0.5 mg/dL for patients with baseline serum creatinine ⩽1.4 mg/dL, an increase of ⩾1.0 mg/dL for patients with baseline serum creatinine > 1.4 mg/dL, or any increase ⩾2 times baseline value. These are sensitive and conservative criteria for determining elevated serum creatinine.

Results: A total of 454 patients completed the 13-month core phase, and 165 patients completed the 12-month extension phase. Baseline serum creatinine was similar between treatment groups, and approximately 95% of patients had normal serum creatinine (<1.4 mg/dL) at study entry. The renal safety profile of 4 mg zoledronic acid was comparable with that of 90 mg pamidronate at 25 months. Overall, 9.4% of patients treated with 4 mg zoledronic acid versus 6.5% of pamidronate-treated patients experienced notable increases in serum creatinine. However, Common Toxicity Criteria (CTC) grade 3 (>3.6 to ⩽7.2 mg/dL) or grade 4 (>7.2 mg/dL) serum creatinine was infrequent. One (0.5%) patient in the pamidronate group developed CTC grade 4 serum creatinine, whereas no patient treated with 4 mg zoledronic acid developed either grade 3 or 4 serum creatinine. Kaplan-Meier analysis of time to first episode of notable serum creatinine increase also showed that 4 mg zoledronic acid was associated with a slightly increased risk of elevated serum creatinine compared with pamidronate, which was not statistically significant (hazard ratio = 1.401; *P*=0.371).

Conclusions: With long-term use (up to 25 months), 4 mg zoledronic acid (via 15-minute infusion) has a renal safety profile comparable with 90 mg pamidronate (via 2-hour infusion) and other IV bisphosphonates.

297 POSTER HIGHLIGHT

Anastrozole therapy and lipid profile: an update

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Background: Endocrine therapy of breast cancer is aimed at inhibiting estrogen-dependent proliferation of cancer cells. Newly developed aromatase inhibitors suppress estrogens synthesis to undetectable levels. The concern exists they might increase the risk of hypoestrogenemia-related disorders, such as disturbances in lipid profile. The current study updates at the prolonged observation our previous results on effects of anastrozole – III generation aromatase inhibitor – on lipid metabolism in tamoxifen pretreated breast cancer patients.

Material and Methods: the study included 51 postmenopausal breast cancer women (median age: 67 years, range: 45–87), who were converted to anastrozole after tamoxifen treatment (median duration of therapy: 76 weeks, range: 14–193). Concentrations of basic blood lipids and body mass index values (BMI = weight in kilograms divided by squared height in meters) were measured at baseline and three times afterwards: at minimum 24 (median: 26, range: 24–33; N=51), 60 (median: 63, range: 60–70; N=51) and 130 (median: 134, range: 130–147; N=25) weeks of anastrozole administration.

Results: there was no statistically significant change over time in basic lipid parameters, that included total- (p=0.51), LDL- (p=0.61), and HDL-cholesterol (p=0.43), triglycerides (p=0.78), the atherogenic risk ratios: total/HDL-cholesterol (p=0.56) and LDL/HDL-cholesterol (p=0.33) as well as in mean BMI values (p=0.93).

Conclusion: anastrozole used in sequence to tamoxifen for approximately 3 years does not affect lipid profile and BMI values of breast cancer patients.

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Safety and convenience of the 15-minute infusion of zoledronic acid

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Background: Highly potent, new-generation bisphosphonates with clinical activity at extremely low molar doses can be administered using short infusion time without compromising renal safety. Among intravenous (IV) bisphosphonates approved for the treatment of hypercalcemia of malignancy (HCM) or bone metastases in patients with breast cancer, zoledronic acid has the shortest recommended infusion time (i.e., 15 min) compared with 1–2 hrs for other agents. Moreover, zoledronic acid has demonstrated clinical benefit superior or equivalent to that of pamidronate in patients with HCM or breast cancer and bone metastases.

Materials and Methods: The safety profile of zoledronic acid (4 mg via 15-min infusion) was compared with that of 90 mg pamidronate (via 2–hr infusion) based on randomized, comparative trials. Comparisons with other bisphosphonates are based on published reports.

Results: Comparative trials of 4 mg zoledronic acid versus 90 mg pamidronate in patients with HCM (N=287) and breast cancer patients with bone metastases (n=1130) have shown that zoledronic acid has an overall and renal safety profile comparable with pamidronate. Commonly reported adverse events – including fever, nausea, fatigue, constipation, and anemia – occurred in a similar proportion of patients