Hot Topic #1: Effects of Diet and Exercise on Mortality and Gene Expression

On Friday morning, Dr. Rowan T. Chlebowski presented an updated subgroup analysis of the Women’s Health Initiative Dietary Modification Trial. The dietary modification goals in this trial included a reduction in intake of calories from fat to 20% and an increase in fruits, vegetables, and grains to 5 to 6 servings/day.

Current analysis of the study looked at deaths directly attributed to BC and deaths after BC. In the cumulative follow-up at 16.1 yr, among 3034 breast cancers, 295 deaths from BC were reported (not statistically significant) and 677 deaths after BC were seen, which reached statistical significance.

Subgroup analysis found that the greatest benefit from dietary intervention was seen in women with waist circumference of >88 cm and women with a dietary intake of >36.8% calories from fat. Women with relatively modest intake of calories from fat (27.9%) had no benefit, suggesting that the threshold for effect is rather high.

There was no difference in stage, tumor size, or positive nodes between the intervention and control groups. However, fewer estrogen receptor-positive/progesterone receptor-negative (PR-) BC were seen in the intervention group, and 27% of this difference was accounted for by the differential effect of diet. Dr. Chlebowski concluded by adding that there was no benefit from dietary intervention in women >70 yr of age.

Next, Dr. Jennifer A. Ligibel, discussed the impact of preoperative exercise on BC gene expression in newly diagnosed women with stage I to III BC. In the Pre-Operative Health and Body Study, 48 eligible participants were randomized to either an exercise intervention with a target goal of 180 min/wk of aerobic activity and 40 min/wk of strength training, or a mind body intervention that required daily reading of a self-directed book, listening to a relaxation CD, and journaling.

Dr. Ligibel’s group performed capture RNA-sequencing of the transcriptome coding regions in 16 pairs of samples. An unsupervised hierarchical clustering analysis showed clustering by PAM50 with separation of basal, luminal, and HER2-enriched subtypes. A differential gene expression analysis showed no significant differential expression in any genes after controlling for multiple comparisons.

It was found that 18 individual pathways were significantly upregulated...
in the exercise group. The cytokine-cytokine receptor interaction pathway was the top upregulated pathway, involving upregulation of genes IL6 and CCL4, and other inflammatory mediators. Some immune pathways, such as the complement and coagulation cascade, were also upregulated. No pathways were upregulated in the mind body group.

Hot Topic #2: AI Side Effects

While aromatase inhibitor-associated musculoskeletal syndrome (AIMSS) occurs in up to 50% of AI-treated patients, only a structured exercise program and acupuncture have been shown to improve symptoms. Dr. N. Lynn Henry and her colleagues studied the treatment of AIMSS with duloxetine (Dul), a serotonin norepinephrine reuptake inhibitor, in women with early stage BC.

The primary objective of this randomized, placebo-controlled trial was to assess whether 12 weeks of Dul decreases average joint pain as assessed with Brief Pain Inventory (BPI) in women with AIMSS. 299 patients were randomized to take Dul or a placebo for 12 weeks.

Results show that those who took Dul reported a lower average joint pain than those taking the placebo by 0.02 points with a p-value of 0.0002. After discontinuation at 12 weeks, the difference decreased, but both groups improved from baseline. At 12 weeks, 69% of those taking Dul reported a clinical significant (2 point) improvement vs. 60% placebo. However, at 24 weeks, 60% Dul reported improvement vs. 59% placebo. The study concluded with a very astounding result: the increase in DFS from 90.8% to 94.3% did not reach statistical significance.

“This reduces average joint pain as assessed with Brief Pain Inventory (BPI) in women with AIMSS. 299 patients were randomized to take Dul or a placebo for 12 weeks.”

Dr. Ligibel added that these findings need to be validated in additional cohorts, and that exercise may have a direct effect on breast tumor tissue in humans.

Hot Topic #3: No Significant Benefit with Ibandronate in Postmenopausal Early BC

According to the TEAM IIB trial, the addition of ibandronate to adjuvant hormone therapy did not improve 3y disease-free survival (DFS) in postmenopausal women with stage I to III hormone receptor-positive (HR+) BC. Treatment was started in the first year of treatment, and patients continued to receive ibandronate. The study concluded that the difference in DFS from 90.8% to 94.3% did not reach statistical significance.

“According to the TEAM IIB trial, the addition of ibandronate to adjuvant hormone therapy did not improve 3y disease-free survival (DFS) in postmenopausal women with stage I to III hormone receptor-positive (HR+) BC.”

Dr. Ganz underscored that existing BC treatments contribute to chronic symptoms that can interfere with the quality of life.

Next, Dr. Patricia A. Ganz highlighted the importance of cardiac safety of AI therapy for chemoprevention. In regards to Dr. Blaes’s study, Dr. Ganz concluded that the increase in DFS from 90.8% to 94.3% did not reach statistical significance.

“According to the TEAM IIB trial, the addition of ibandronate to adjuvant hormone therapy did not improve 3y disease-free survival (DFS) in postmenopausal women with stage I to III hormone receptor-positive (HR+) BC.”

Dr. Ganz underscored that existing BC treatments contribute to chronic symptoms that can interfere with the quality of life.

Hot Topic #4: Effects of Diet and Exercise on Mortality and Gene Expression

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