Secondary malignancies (SM) represent one of the potential hazards of modern cancer treatment and especially of radio- and chemotherapy after surgery for breast cancer. For this reason, regional tumor registry data (1960-1975) on 1985 breast cancer patients were analyzed for SM in the retrospective part of our study. These data were compared with the prospective part of the study in which 241 patients were randomly assigned to either mastectomy or mastectomy and chemoimmunotherapy (CT + IT). In the retrospective part of the study, SM were observed in 83 cases (4.2%), 49% of which were SM of the contralateral breast. Most frequent extramammary SM were of gastrointestinal (25%), gynecologic (8%) and cerebral (5%) origin. Leukemias were found in 4% of all SM. Median time interval to SM was 5 years and 1 month. Within 5, 10 and 15 years after mastectomy 60%, 85% and 95% of SM were observed respectively. Median survival of patients with SM was 6 1/2 years. In the prospective part of the study, SM were observed in 9 cases (3.7%), 4.1% in the surgical control group and 3.4% in the adjuvant CT + IT group with a median observation time of 6 years post mastectomy. These data are compared to other current adjuvant breast trials and do not indicate as of now an increase in SM under present adjuvant therapy.