g. HRQoL in breast cancer

Perry et al. (50) summarized the HRQoL instruments, about 20 in all, that have been used in clinical trials on breast cancer. The following comments focus on only two trials, namely, the Watanabe study and the Muss study.

1. Where survival data are identical in both study arms, HRQoL data turn the tide – the Watanabe study

Watanabe et al. (51) provide an elegant narrative regarding HRQoL data for a clinical study of women, after surgery, who received either uracil plus tegafur (UFT) (group 1), or cyclophosphamide, methotrexate, and 5-fluorouracil (CMF) (group 2). The study shows graphs of various measures of quality of life for the two groups over a 2-year period. For example, one graph disclosing the parameter of "upset by hair loss," shows that the CMF group peaked at 1–4 months, and then returned towards baseline while, in contrast, the UFT group remained at baseline.

Data on survival for the UFT group and the CMF group were essentially identical. In view of these identical results, the authors turned to the HRQoL data for guidance. In finding the quality of life data to be better in the UFT group, the authors recommended UFT, over CMF, as the proper treatment for breast cancer. Thus data on HRQoL played a role in concluding that one of the study arm treatments was better than the other.

The following concerns prognostic factors. There has been some interest in using HRQoL data, for example, on fatigue and emotional states, acquired before drug treatment is initiated, as a prognostic factor for later-arising parameters of efficacy (52,53).

2. HRQoL data demonstrate that long-term treatment is well tolerated – the Muss clinical trial

HRQoL data were evaluated for a drug that was intended for chronic administration, and used to prevent recurrence of breast cancer. Muss et al. (54) studied breast cancer

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