

TABLE 22.4 HRQoL Results From the Shepherd Study

	Erlotinib (Study Drug)			Placebo			P Value (Significance of Difference Between Study Drug and Placebo)
	Improved	Stable	Worsen	Improve	Stable	Worsen	
Pain	42	15	43	28	20	51	0.01
Dyspnea	34	27	40	23	33	44	0.03
Cough	44	24	32	27	31	41	0.00
Fatigue	45	4	51	36	8	55	0.06
Emotional	39	24	37	30	36	35	0.01

for example, Portuguese (48), Chinese (49), German (50), and Italian (51).

2. The Bezzak Study

Bezzak et al. (52) reported one particularly useful aspect of HRQoL, namely, that the adverse influence of study drug on HRQoL was only temporary. Hence, this result might influence the decisions of the physicians and patients to request this chemotherapy. In the author's words, "[f]unctional impairment is not unusual for individuals who are taking chemotherapy ... however, by 9 months, when most of the acute adverse effects of chemotherapy have resolved, there is a return to normal function. The only persistent symptom scale score differences, specifically peripheral neuropathy and ototoxicity."

The Bezzak study provides an excellent demonstration of good methodology. If the investigator wishes to capture HRQoL data, it is poor methodology to administer the HRQoL tool only at one time, and good methodology to administer the HRQoL tools at two or three different time points during the course of the clinical trial.

3. The Bonomi Study

The Bonomi clinical trial reveals a problem that might arise, where the HRQoL tool is administered at several different times during the course of the study. In a clinical trial of lung cancer, Bonomi et al. (53) collected information on HRQoL. These authors documented the problem that, as the clinical study progressed, compliance with filling out the

⁴⁸Pais-Ribeiro J, Pinto C, Santo C. Validation study of the Portuguese version of the QLC-C30-V.3. *Psicologia, Saude & Doencas* 2008;9:89–102.

⁴⁹Wan C, Meng Q, Yang Z, et al. Validation of the simplified Chinese version of EORTC QLQ-C30 from the measurements of five types of inpatients with cancer. *Ann. Oncol.* 2008;19:2053–60.

⁵⁰Bestmann B, Rohde V, Siebmann JU, Galalae R, Weidner W, Kuchler T. Validation of the German prostate-specific module. *World J. Urol.* 2006;24:94–100.

⁵¹Zotti P, Lugli D, Vaccher E, Vidotto G, Franchin G, Barzan L. The EORTC quality of life questionnaire-head and neck 35 in Italian laryngectomized patients. *European organization for research and treatment of cancer. Qual. Life Res.* 2000;9:1147–53.

⁵²Bezzak A, Lee CW, Ding K, et al. Quality-of-life outcomes for adjuvant chemotherapy in early-stage non-small-cell lung cancer: results from a randomized trial, JBR.10. *J Clin Oncol.* 2008;26:5052–9.

⁵³Bonomi P, Kim K, Fairclough D, et al. Comparison of survival and quality of life in advanced non-small-cell lung cancer patients treated with two dose levels of paclitaxel combined with cisplatin versus etoposide with cisplatin: results of an Eastern Cooperative Oncology Group trial. *J. Clin. Oncol.* 2000;18:623–31.