



Figure 14.8 Comparison of lipid parameters between patients who switched to FTC/RPV/TDF at baseline and those who maintained a PI + RTV + two NRTIs regimen in the SPIRIT study at week 24.

and other considerations that are not captured by standard laboratory evaluations. Several validated tools are available to quantify outcomes such as quality of life, preference of medication, ease of regimen, treatment satisfaction, treatment intrusiveness and symptoms associated with HIV or its treatment.^{40–44} Table 14.3 describes some of the common tools used to measure patient-reported outcomes in clinical trials. Several studies that have utilized these tools have shown significant improvements in patient-reported outcomes for STRs compared with other ARV treatment regimens.

Patients who switched to EFV/FTC/TDF reported better outcomes than patients who stayed on NNRTI- or PI-based regimens in Study 073. Results from the Preference of Medication (POM) survey for the EFV/FTC/TDF arm showed that more patients preferred EFV/FTC/TDF over their previous regimen at all post-baseline visits ($p < 0.001$) and at week 48, 85% of patients stated that EFV/FTC/TDF was ‘much better’ than their previous regimen. According to the Perceived Ease of Regimen for Condition (PERC) questionnaire, 68% of EFV/FTC/TDF patients *versus* 75% of SBR patients considered their regimen ‘very easy to take’ at baseline compared with 97% and 81% at week 48 ($p < 0.001$). Patients in the EFV/FTC/TDF arm also had a statistically significant improvement from baseline in the physical component summary of the health-related quality of life [Medical Outcomes Study 36-item Short Form (SF-36)] survey at week 48 ($p = 0.010$). Finally, self-reported symptoms from the HIV Symptom Index through week 48 demonstrated improvements in diarrhea/loose bowel movements ($p = 0.007$), bloating, pain or gas in the stomach ($p = 0.001$), changes in body appearance ($p = 0.002$) and problems having sex ($p = 0.032$) with EFV/FTC/TDF whereas patients who stayed on their NNRTI- or PI-based regimen had no significant changes.^{35,40}

Patients who switched to the FTC/RPV/TDF STR experienced improvements in self-reported outcomes compared with remaining on a PI + RTV + two NRTIs regimen after 24 weeks in the SPIRIT study. Results from the HIV Symptom Index demonstrated that fewer patients who switched