with hypercholesterolemia (total cholesterol $\geq 200\,mg\,dL^{-1}$) was designed to determine the impact of switching from ABC/3TC + EFV to EFV/FTC/TDF ($n = 79$) *versus* continuing on ABC/3TC + EFV ($n = 78$). At week 12, patients receiving EFV/FTC/TDF continued for an additional 12 weeks of treatment, whereas those receiving ABC/3TC + EFV switched to EFV/FTC/TDF. Patients who switched to EFV/FTC/TDF experienced significant median reductions in fasting lipid parameters after 12 weeks than patients continuing on ABC/3TC + EFV, including decreased TC (–33.6 *versus* +0.4 $mg\,dL^{-1}$; primary endpoint), LDL (–22.0 *versus* –0.8 $mg\,dL^{-1}$), HDL (–5.0 *versus* +1.5 $mg\,dL^{-1}$) and TG (–24.8 *versus* –2.7 $mg\,dL^{-1}$); $p < 0.001$ for all results**.** Decreases in lipid parameters at week 12 were similarly maintained at week 24 for patients who switched to EFV/FTC/TDF at baseline. The TC:HDL ratio was similar for the two treatment arms at both 12 and 24 weeks**.** Patients who switched to EFV/FTC/TDF at week 12 experienced median reductions in fasting lipid parameters from week 12 to week 24 similar to those observed in patients receiving EFV/FTC/TDF for 24 weeks**.** Renal parameters were similar between arms and within the normal range through week 24.[37,38]

The FTC/RPV/TDF STR was well tolerated through week 24 in Study 111, the single-arm study of patients who switched from EFV/FTC/TDF to FTC/RPV/TDF for tolerability issues. No subjects had AEs leading to study drug discontinuation through 24 weeks. The majority of study drug-related AEs were grade 1 in severity and there were no grade 3 or 4 AEs. Median changes from baseline in fasting lipid parameters were significantly improved for TC (–24 $mg\,dL^{-1}$; $p < 0.001$) and LDL cholesterol (–17 $mg\,dL^{-1}$; $p < 0.001$) through week 24.[33]

Switching to the FTC/RPV/TDF STR resulted in improvements in lipid parameters and cardiovascular risk compared with staying on a PI-based regimen through 24 weeks in the SPIRIT study, the Phase 3b study evaluating switching to FTC/RPV/TDF from PI + RTV + two NRTIs. At week 24, rates of grade 3 or 4 AEs and grade 3 or 4 laboratory abnormalities were similar in patients who switched to FTC/RPV/TDF at baseline and those who stayed on PI + RTV + two NRTIs (AEs, 5.0% *versus* 6.9%; laboratory abnormalities, 6.3% *versus* 11.3%). Reductions in lipid parameters were significantly greater for patients who switched to FTC/RPV/TDF including TC (–25 *versus* –1 $mg\,dL^{-1}$), LDL (–16 *versus* 0 $mg\,dL^{-1}$), HDL (–4 *versus* –1 $mg\,dL^{-1}$), TG (–53 *versus* +3 $mg\,dL^{-1}$) and TC:HDL ratio (–0.27 *versus* +0.08); $p < 0.001$ for all comparisons (Figure 14.8). Switching to FTC/RPV/TDF also resulted in a significant improvement in 10 year Framingham Risk Score for cardiovascular disease ($p = 0.001$).[39]

14.6 Patient-reported Outcomes

With an increasing number of safe and effective ARV options, maintaining or improving patient satisfaction and quality of life has become an increasingly important goal of ARV therapy.[40] Patient-reported outcomes have been incorporated into clinical trials more frequently to assess patient perceptions