

Strosberg, J., Wolin, E., Chasen, B., Kulke, M., Bushnell, D., Caplin, M., Baum, R.P., Kunz, P., Hobday, T., Hendifar, A. and Oberg, K., 2018. **Health-Related Quality of Life in Patients With Progressive Midgut Neuroendocrine Tumors Treated With ¹⁷⁷Lu-Dotatate in the Phase III NETTER-1 Trial.** *Journal of Clinical Oncology*, pp.JCO-2018.

Abstract

Purpose Neuroendocrine tumor (NET) progression is associated with deterioration in quality of life (QoL). We assessed the impact of ¹⁷⁷Lu-Dotatate treatment on time to deterioration in health-related QoL. **Methods** The NETTER-1 trial is an international phase III study in patients with midgut NETs. Patients were randomly assigned to treatment with ¹⁷⁷Lu-Dotatate versus high-dose octreotide. European Organisation for Research and Treatment of Cancer quality-of-life questionnaires QLQ C-30 and G.I.NET-21 were assessed during the trial to determine the impact of treatment on health-related QoL. Patients completed the questionnaires at baseline and every 12 weeks until tumor progression. QoL scores were converted to a 100-point scale according to European Organisation for Research and Treatment of Cancer instructions, and individual changes from baseline scores were assessed. Time to QoL deterioration (TTD) was defined as the time from random assignment to the first QoL deterioration ≥ 10 points for each patient in the corresponding domain scale. All analyses were conducted on the intention-to-treat population. Patients with no deterioration were censored at the last QoL assessment date. **Results** TTD was significantly longer in the ¹⁷⁷Lu-Dotatate arm (n = 117) versus the control arm (n = 114) for the following domains: global health status (hazard ratio [HR], 0.406), physical functioning (HR, 0.518), role functioning (HR, 0.580), fatigue (HR, 0.621), pain (HR, 0.566), diarrhea (HR, 0.473), disease-related worries (HR, 0.572), and body image (HR, 0.425). Differences in median TTD were clinically significant in several domains: 28.8 months versus 6.1 months for global health status, and 25.2 months versus 11.5 months for physical functioning. **Conclusion** This analysis from the NETTER-1 phase III study demonstrates that, in addition to improving progression-free survival, ¹⁷⁷Lu-Dotatate provides a significant QoL benefit for patients with progressive midgut NETs compared with high-dose octreotide.