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Digital Therapeutics for Hypertension and Chronic Kidney Disease

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Digital Therapeutics (DTx) provides a novel therapeutic option that delivers disease treatment through digital devices. Specifically, DTx that installs therapeutic software into digital devices are known as "treatment apps." As of April 2024, in Japan, DTx has received approval for three disease areas: smoking cessation, essential hypertension, and insomnia. This lecture focuses on a DTx app designed for hypertension, closely relates to chronic kidney disease, aimed at controlling high blood pressure through various lifestyle modification. The hypertension DTx app was developed to efficiently support lifestyle modification, a non-pharmacological therapy recommended for all patients with hypertension according to the hypertension guidelines. It bridges the treatment gaps between outpatient visits by providing educational contents on hypertension and its complications via the app, and by managing daily blood pressure monitoring through automatic sync with home blood pressure devices. The goal is to maximize clinical performance through lifestyle modification. In the HERB-DH1 pivotal trial, which examined the efficacy of the DTx app on improving blood pressure in patients with essential hypertension, the difference of the change in the 24-hour systolic blood pressure from baseline (0 weeks) to week 12 was -2.4 mmHg ($P=0.024$). The DTx app-using intervention group showed a significantly greater reduction in systolic blood pressure compared to the control group, and this effect continued at least for 24 weeks. Furthermore, an analysis using the practice-based real-world data of the 1000 DTx app users also showed a significant blood pressure-lowering effect at 12 (-4.9 mmHg) and 24 weeks (-6.1 mmHg) when compared to baseline blood pressure, even in various subgroups, including users aged 65 and older and those under medication at baseline, who were excluded from the previous clinical trial. We look forward to the continued expansion of DTx as one of the effective options to support hypertension treatment.



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