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COMMENT

CureAPP HT is expected to be one piece of the puzzle that physicians and patients can work together to solve the problem of uncontrolled hypertension

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For physicians, overcoming the "*Hypertension paradox*" is a challenge in order to reduce future cardiovascular events in their hypertensive patients. Although the number of drug treatment options has increased over the past decade, the number of well-controlled hypertension patients remains insufficient. One possible reason for this is that there has been insufficient intervention in lifestyle habits, especially among the younger generation. To resolve this situation, it is important to have hypertension treatment strategies that combines not only drug therapy but also sufficient sustainable non-pharmacological therapy. In particular, obesity and excessive salt intake are recognized to be related to poorly controlled hypertension, including early morning and nighttime blood pressure, and therefore are lifestyle habits that physicians and patients must address and intervene in together over the long term. However, even if these factors are known to be important risk factors for hypertension, it is difficult to secure sufficient time to provide lifestyle guidance in practice, and not all practitioners are able to practice it. On the other hand, the lack of standardization of life guidance programs makes also them difficult to continue. Now, methods and tools that can standardize sustainable non-pharmacological therapy are needed.

Against this background, Kario et al. reported the HERB Digital Hypertension 1 (HERB-DH1) study [1]. This study was conducted as a domestic Phase III study and was a multicenter randomized controlled trial to evaluate the safety and efficacy of adding the HERB system to standard treatment in 390 patients with essential hypertension. Among hypertensive patients aged 20 years or older and younger than 65 years, who were not receiving oral antihypertensive treatment, the efficacy and safety were compared between the app intervention group and the control group at 12 weeks after clinical trial registration. In other words, both groups received guidance on lifestyle modification in accordance with the Hypertension Treatment Guidelines 2019 [2] as standard hypertension treatment, and the effect of this treatment app was evaluated after that. As a result of the primary endpoint, the intervention group using this treatment app showed a significant antihypertensive effect compared to the control group in the 24-h average systolic blood pressure based on ambulatory blood pressure monitoring (ABPM) at 12 weeks of treatment (−4.9 vs. 2.5 mmHg, respectively). Furthermore, the antihypertensive effect of this treatment app was also evident especially in morning systolic blood pressure compared to the control group (−10.6 vs. −6.2 mmHg, respectively). In the J-HOP study targeting Japanese people at cardiovascular risk, it was shown that a 10 mmHg increase in morning home systolic blood pressure increases the risk of stroke by 36% [3]. Therefore, a 10.6 mmHg decrease in early morning home systolic blood pressure by using the treatment app is expected to suppress future cardiovascular events. These research results make it possible to continue non-pharmacological treatment, which had not been standardized until now, regardless of who uses the app.

What specifically has changed and improved by using the treatment app? Because hypertension is a lifestyle-related disease, if physicians do not fully understand not only the patient's blood pressure numbers but also the lifestyle habits behind them, they will not be able to analyze why the blood pressure has risen and will not be able to select the appropriate antihypertensive drug for the condition. This accumulation is thought to be a factor that leads to the "*Hypertension paradox*" and "*Clinical inertia*". To

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solve this problem, Katsuya et al. [4] focused on CureAPP HT, the predecessor of the HERB system, which was approved for insurance reimbursement in September 2022 for the first time in the world. CureAPP HT is a medical device program that aims to assist physicians in their treatment by providing patients with essential hypertension with comprehensive and individualized lifestyle modifications such as salt reduction, weight loss, exercise, drinking less, sleep, and stress management. Patients enter their daily blood pressure reduction-related behavior practice status along with their home blood pressure, and physicians view it during consultations and provide appropriate advice. This allows physicians and patients to set blood pressure reduction goals necessary for hypertension treatment, share the progress of lifestyle improvements and their habituation, and proceed with treatment. CureAPP HT actually has become possible to make the physician-patient relationship more effective and deeper than before. Katsuya et al. quantitatively evaluated the physician-patient relationship by scoring 13 questions in three phases for practicing physicians who had introduced CureAPP HT for the first time. The main interpretation of the results is that patients deepened their knowledge of hypertension treatment and became more motivated, and this change had a positive effect on physicians, leading them to aim for stricter blood pressure targets. Moreover, it is expected that this will lead to behavioral changes not only for patients but also for physicians themselves. Shared-Decision-Making, which has been attracting particular attention in recent years, cannot be achieved if there is a discrepancy between the physician and the patient regarding the disease. This perspective is particularly important in hypertension treatment, which requires long-term follow-up. Specifically, rather than simply increasing or adding antihypertensive drugs unilaterally, the choice should be made together with the patient. CureAPP HT is an opportunity to correct such discrepancies between physicians and patients.

What kind of patients would benefit from CureAPP HT? Kario et al. reported that in the HERB-DH1 study, patients with a baseline BMI of 25 kg/m2 or more and high salt intake (self-reported salt intake score [5] ≧14) had a particularly low early morning home blood pressure (−5.1 mmHg) [6]. Furthermore, they reported that when BMI was reduced and self-reported salt intake score was improved, early morning home blood pressure was significantly reduced (−7.2 mmHg) compared to the control group. From this result, “BMI” and “salt” are factors that predict whether a patient will especially respond to CureAPP HT. Obesity is a risk factor for salt-sensitive hypertension [7], and excessive salt intake may further increase blood pressure and lead to the development of cardiovascular events. It is a synergistic effect, not an additive effect. In 2020, Tsuchihashi et al. published the JSH Tokyo declaration at the Japanese Society of Hypertension [8], proposing that salt reduction should be a goal not only for individuals but for society as a whole. However, since then, the spread of COVID-19 has led to people staying at home and less exercise, which has resulted in an increase in the number of obese people and more opportunities to consume high-salt foods through delivery food. In addition, the number of people receiving specific health checkups and specific health guidance has decreased since the start of the program, and it is predicted that the number of hypertensive patients with high salt sensitivity will increase in the future. Against this background, CureAPP HT may be considered one of the device treatments that can shift salt-sensitive hypertension to salt-insensitive hypertension by improving physician-patient communication and clinical inertia.

I would like to discuss the future developments and challenges of CureAPP HT. First, the period for which Cure APP HT, which is currently approved for insurance coverage in Japan, can be introduced is six months. Therefore, after six months, the physician-patient relationship will be maintained in the traditional way. If CureAPP HT can no longer be used, will this relationship reduce the effectiveness of non-pharmacological therapy? I do not think so. Fortunately, from June 2024, treatment plans for calculating lifestyle-related disease management fees will be created in daily medical practice, mainly by practicing physicians. This is exactly a continuation of app therapy, and since it has simply changed from smartphones to paper, it is possible to continue non-pharmacological therapy visually even after app therapy has ended. Next, what about the cost-effectiveness? Nomura et al. used HERB-DH1 data to examine the cost-effectiveness of digital therapeutics and reported their usefulness compared to traditional lifestyle guidance alone [9]. On the other hand, it has been reported that in low-risk mild hypertensive patients, prescribing antihypertensive drugs from the start of treatment has no benefit in preventing the onset of CVD events [10]. Therefore, if digital therapeutics are cost-effective, we believe that the introduction of CureAPP HT in this low-risk mild hypertensive patients is a good indication. Finally, although the positioning of CureAPP HT in clinical practice is understood in this way, what has not yet been verified is its efficacy and safety in patients aged 65 years or older. Since the target age of the HERB-DH1 trial is 20 to 64 years old, evidence in patients aged 65 years or older is desired in the future. In particular, we would like to wait for verification of the effectiveness of non-pharmacological therapy in so-called active seniors who can use smartphones, as it is expected to be effective.

Aiming for well-controlled hypertension is a puzzle that requires collaboration between physicians and patients (Fig. 1). CureAPP HT is an important piece of the puzzle.

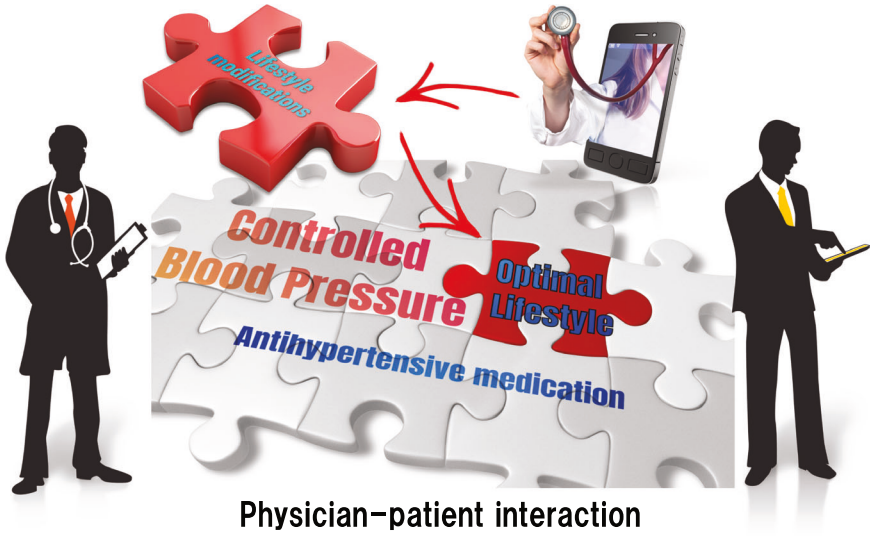

Fig. 1 An important piece of the puzzle of well-controlled hypertension

When the puzzle is completed, the "*Hypertension paradox*" will be resolved.

Compliance with ethical standards

Conflict of interest The author declares no competing interests.

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