Questionnaire Survey From the Viewpoint of Concordance in Patient and Physician Satisfaction Concerning Hypertensive Treatment in Elderly Patients —Patients Voice Study—

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Background: Patient-physician concordance is an important concern in the treatment of elderly patients with hypertension (HT). Treatment that considers concordance is necessary for mutual understanding and therapeutic satisfaction between patients and physicians. However, there have been no studies addressing concordance that objectively analyzed both patient and physician satisfaction before and after treatment.

Methods and Results: An exploratory open-label, multicenter, intervention study was conducted. Patients with HT undergoing treatment with angiotensin-receptor blocker (ARB) or a calcium-channel blocker (CCB) monotherapy were enrolled. Medication was switched to an ARB/CCB combination tablet and taken for 12 weeks. Physicians and patients participated in satisfaction surveys concerning treatment. Discrepancies in satisfaction levels between patients and physicians were found at baseline for the following survey items: treatment, involvement in treatment, understanding of HT, reliance, medication, and blood pressure. After treatment, the satisfaction levels of both patients and physicians increased; discrepancies in satisfaction between the groups also improved.

Conclusions: The rates of satisfaction were relatively higher for patients compared with physicians at baseline. After HT treatment addressing concordance, both patient and physician satisfaction rates and the gap in satisfaction rates between patients and physicians improved. This indicates that addressing concordance has clinical significance in the treatment of elderly HT patients.

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Key Words: Combination treatment; Elderly patients; Hypertension; Patient-physician concordance

Japan is a super-aged society in which the elderly over 65 years of age accounted for 27.3% of population in 2016.1 In the elderly patients with hypertension (HT), medical intervention should aim to either maintain or prevent a decline in activities of daily living, and the prevention of cardiovascular disease is consistent with this purpose.2 However, HT does not exhibit marked symptoms and a treatment-related decrease in blood pressure (BP) is often misunderstood as a cure of HT and treatment is discontinued in some cases.3,4 Thus, it is necessary for the patient to clearly understand HT, the treatment objectives, and the treatment methods,5–9 and this knowledge is expected to contribute to patients’ satisfaction. On the other hand, discrepancy in the perception of expectations for treatment between patients and physicians has been reported.10 Thus, treatment should take into consideration the patient-physician concordance. Concordance involves patient-physician discussions conducted on an equal footing with treatment strategies based on mutual agreement. The influence of HT treatment that addresses concordance

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of both patient and physician satisfaction is unknown. Furthermore, to the best of our knowledge, there have been no evaluations reported on the satisfaction with treatment of both the patient and the attending physician before and after a therapeutic intervention that addresses also concordance.

A combination drug reportedly contributes to improved adherence and patient quality of life (QOL).\textsuperscript{11-14} In the Japanese Society of Hypertension 2014 Guidelines for the Management of Hypertension (JSH2014), combination therapy with a calcium-channel blocker (CCB), an angiotensin-receptor blocker (ARB) or an angiotensin-converting-enzyme inhibitor, and a low-dose diuretic is recommended as the first-line treatment in elderly patients with HT.\textsuperscript{15} Considering this, an exploratory study was conducted to evaluate the satisfaction of both elderly HT patients and physicians and patient QOL before and after an ARB/CCB combination drug treatment that included a focus on concordance.

This study was conducted in accordance with the ethical principles of the Declaration of Helsinki and the ethical guidelines for clinical studies of the Ministry of Health, Labour and Welfare in Japan and the guideline for good clinical practice of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (UMIN000017270).

**Methods**

**Study Design**

An exploratory open-label, multicenter, intervention study was conducted at 22 sites in Kagoshima, Japan, from April 2015 to December 2016 with enrollment from September 2015 to September 2016. A central enrollment system was used. Patient enrollment and data collection were conducted using an electronic data capture system, centered in Tokyo at Sogo Rinsho Medefi Co., Ltd. This study consisted of a screening phase and a treatment phase. The study design is shown in Figure 1. Patients who met the inclusion criteria were enrolled in the screening phase and administered an ARB or CCB for at least 8 weeks. Patient BP was measured at the clinic and at the patient’s home using home BP monitoring equipment. After receiving monotherapy of ARB or CCB for at least 8 weeks, patients who did not achieve their age-based target BP were enrolled in the treatment phase and their medication switched to an ARB/CCB combination tablet taken for 12 weeks. During the treatment phase, physicians and patients separately participated in satisfaction surveys concerning HT treatment and patients also participated in a QOL survey; these surveys were conducted at baseline and at 12 weeks. This study was approved by the institutional review board at each study site. Written informed consent was given by all patients before enrollment.

**Interventions**

The pretreatment drug in the screening phase was 20 mg/day of olmesartan medoxomil, an ARB, or 16 mg/day of azelnidipine, a CCB, and the study drug in the treatment phase was an olmesartan medoxomil/azelnidipine combination tablet (ARB/CCB combination tablet) (Figure 1). Both the pretreatment drugs and the study drug were taken every morning after breakfast. The target BP was determined according to JSH 2014. If the age-based target BP differed from the target BP based on the presence of a complication, the age-based target BP was set as the first goal and a lower target BP based on the presence of a complication would be the aim if tolerated.\textsuperscript{2} If an excessive decrease in BP occurred during the study, the study drug was changed to monotherapy of 20 mg/day of olmesartan medoxomil or 16 mg/day of azelnidipine. If an excessive decrease in BP occurred after switching to monotherapy, the treatment drug was discontinued. Antihypertensive medications other than the study drug taken prior to the start of the
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A. Satisfaction survey for patients

For Questions 1 through 10, circle the most appropriate response:

| Question | Strongly agree | Agree | Somewhat agree | Somewhat disagree | Strongly disagree |
|----------|----------------|-------|----------------|-------------------|-------------------|
| Q1. Satisfaction with treatment | 1 | 2 | 3 | 4 | 5 |
| Q2. Involvement in treatment | 1 | 2 | 3 | 4 | 5 |
| Q3. Understanding of HT | 1 | 2 | 3 | 4 | 5 |
| Q4. Understanding of explanation of HT | 1 | 2 | 3 | 4 | 5 |
| Q5. Reliance | 1 | 2 | 3 | 4 | 5 |
| Q6. Antihypertensive drug | 1 | 2 | 3 | 4 | 5 |
| Q7. Clinic BP | 1 | 2 | 3 | 4 | 5 |
| Q8. Home BP | 1 | 2 | 3 | 4 | 5 |
| Q9. Perception of target BP | 1 | 2 | 3 | 4 | 5 |
| Q10. Target BP level | 1 | 2 | 3 | 4 | 5 |

B. Satisfaction survey for physician

For Questions 1 through 10, circle the most appropriate response:

| Question | Strongly agree | Agree | Somewhat agree | Somewhat disagree | Strongly disagree |
|----------|----------------|-------|----------------|-------------------|-------------------|
| Q1. Satisfaction with treatment | 1 | 2 | 3 | 4 | 5 |
| Q2. Involvement in treatment | 1 | 2 | 3 | 4 | 5 |
| Q3. Understanding of HT | 1 | 2 | 3 | 4 | 5 |
| Q4. Understanding of explanation of HT | 1 | 2 | 3 | 4 | 5 |
| Q5. Reliance | 1 | 2 | 3 | 4 | 5 |
| Q6. Antihypertensive drug | 1 | 2 | 3 | 4 | 5 |
| Q7. Clinic BP | 1 | 2 | 3 | 4 | 5 |
| Q8. Home BP | 1 | 2 | 3 | 4 | 5 |
| Q9. Perception of target BP | 1 | 2 | 3 | 4 | 5 |
| Q10. Target BP level | 1 | 2 | 3 | 4 | 5 |

Figure 2. Satisfaction survey forms for (A) patients and (B) physicians. BP, blood pressure; HT, hypertension.

Study Subjects

Inclusion criteria for the screening phase were: (1) Grade 1 (systolic BP (SBP): 140–159 and/or diastolic BP (DBP): 90–99 mmHg) or Grade 2 (SBP: 160–179 and/or DBP: 100–109 mmHg) essential HT; (2) able to take a daily olmesartan medoxomil 20mg tablet or azelnidipine 16mg tablet for at least 8 weeks; (3) ≥65 years old and (4) outpatient status.

Eligibility criteria for the treatment phase were: (1) taken olmesartan medoxomil 20mg tablets daily or azelnidipine 16mg daily for at least 8 weeks during the screening phase; and (2) not reached age-based target BP: 65–74 years, ≥135/85 mmHg (home BP); >75 years of age, ≥145/85 mmHg (home BP); 65–74 years: ≥140/90 mmHg (clinic BP); >75 years, ≥150/90 mmHg (clinic BP).

For diagnostic discrepancies between clinic and home BP data, the home BP-based measurements were used. For diagnostic discrepancies between Medicallink home BP and BP log entries, the Medicallink-based home BP data
were used. Home BP measurements were determined according to the mean values of the 2 readings taken each morning and evening over the most recent 5 days.

Exclusion criteria for the screening phase were: (1) moderate or severe cognitive impairment determined by the principal investigator or sub-investigator using a comprehensive geriatric assessment simplified version (CGA7); (2) taking medication to treat dementia; (3) prior cerebrovascular disorder in the 6 months before informed consent; (4) unable to complete a 6-m walk test; (5) taking an

| Table 1. Patients’ Backgrounds in Study of Patient-Physician Concordance |
|-----------------------------------------------|
| **Total** | **<75 years** | **≥75 years** |
|-----------------|-------------|-------------|
| Subjects, n (%) | 85 | 43 (50.6) | 42 (49.4) |
| Age (years), mean ± SD | 75.3±6.7 | 70.0±3.1 | 80.8±4.7 |
| Height (cm), mean ± SD | 155.2±9.6 | 159.5±7.7 | 150.9±9.6 |
| Body weight (kg), mean ± SD | 58.6±10.6 | 62.7±10.2 | 54.3±9.2 |
| Sex, n (%) | | | |
| Male | 37 (43.5) | 25 (58.1) | 12 (28.6) |
| Female | 48 (56.5) | 18 (41.9) | 30 (71.4) |
| History of cerebrovascular disease, n (%) | 2 (2.4) | 1 (2.3) | 1 (2.4) |
| Complications, n (%) | 41 (48.2) | 23 (53.5) | 18 (42.9) |
| eGFR (mL/min/1.73m²) | | | |
| ≥60 | 40 (52.6%) | 26 (70.3%) | 14 (35.9%) |
| <60 | 36 (47.4%) | 11 (29.7%) | 25 (64.1%) |
| Previous antihypertensive drugs, n (%) | | | |
| Olmesartan medoxomil 20 mg | 48 (56.5) | 26 (60.5) | 22 (52.4) |
| Azelnidipine 16 mg | 37 (43.5) | 17 (39.5) | 20 (47.6) |
| Concomitant antihypertensive drugs, n (%) | 11 (12.9) | 5 (11.6) | 6 (14.3) |
| Classification of BP, n (%) | | | |
| Normal range | 12 (14.1) | 7 (16.3) | 5 (11.9) |
| Grade I | 45 (52.9) | 27 (62.8) | 18 (42.9) |
| Grade II | 22 (25.9) | 8 (18.6) | 14 (33.3) |
| Grade III | 6 (7.1) | 1 (2.3) | 5 (11.9) |
| Home BP (mmHg), mean ± SD | | | |
| Early morning SBP | 157.3±19.7 | 151.9±12.3 | 162.6±23.7 |
| Early morning DBP | 87.2±10.2 | 89.4±8.5 | 85.1±11.4 |
| Evening SBP | 142.9±19.7 | 138.2±17.5 | 147.7±20.8 |
| Evening DBP | 78.0±10.7 | 79.1±11.0 | 77.0±10.7 |
| Clinic BP (mmHg), mean ± SD | | | |
| SBP | 159.1±20.6 | 152.6±15.4 | 165.7±23.2 |
| DBP | 80.2±12.1 | 83.2±10.4 | 77.0±13.1 |
| Pulse rate (beats/min), mean ± SD | | | |
| Early morning | 65.7±10.2 | 66.7±10.0 | 64.8±10.3 |
| Evening | 69.6±10.6 | 71.7±10.3 | 67.5±10.5 |
| At clinic | 72.0±9.1 | 72.9±9.2 | 71.1±9.0 |
| SF-12 score, mean ± SD | | | |
| Physical component summary | 38.3±16.1 | 40.1±14.5 | 36.5±17.6 |
| Mental component summary | 56.7±9.4 | 54.0±8.3 | 59.7±9.6 |
| Role/social health component summary | 48.5±12.5 | 51.6±10.6 | 45.1±13.6 |
| Physical functioning | 40.9±15.5 | 43.4±13.7 | 38.2±17.1 |
| Role-physical | 42.5±12.7 | 44.8±11.6 | 40.1±13.5 |
| Bodily pain | 43.0±13.5 | 45.1±14.1 | 40.9±12.6 |
| General health | 50.7±12.2 | 48.5±11.7 | 53.1±12.4 |
| Vitality | 54.2±10.6 | 52.2±10.2 | 56.2±10.8 |
| Social functioning | 50.0±10.8 | 52.9±8.9 | 47.0±13.1 |
| Role-emotional | 48.8±10.4 | 49.6±8.8 | 48.0±12.0 |
| Mental health | 52.9±9.5 | 52.6±8.9 | 53.2±10.2 |
| VAS score, mean ± SD | | | |
| Health status | 70.0±21.3 | 70.0±18.5 | 70.1±24.2 |
| Happiness status | 78.0±21.4 | 76.2±19.6 | 79.8±23.3 |

BP, blood pressure; SF-12, Short Form 12-item health survey; VAS, visual analog scale.
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The study period were collected. An AE was defined as any unfavorable or unintended sign, symptom, or disease that occurred during the treatment phase.

Observations and Assessments
The following information was collected as patient background data: age, sex, height, weight, complications, and medical history. Clinic BP was taken at least twice during each visit. The patient satisfaction form, SF-12, and VAS were handed to patients by other than physicians at each institute. After completion by the patient, all forms were put in a sealed envelope and submitted to the clerk. At the week 12 visit, patient compliance with the study treatment was confirmed by the investigators.

Statistical Analysis
Efficacy endpoints were analyzed in the full analysis set (FAS); for the primary endpoints, the result of analysis in the per-protocol set (PPS) was referenced. The FAS was defined as the population that included all patients with the exception of the following: (1) patients who did not take study drug during the treatment phase and (2) patients with no data or unavailable data at baseline or week 12. The PPS was defined as the FAS population except for the following patients: (1) failure to meet the requirements of the inclusion criteria, (2) <80% compliance with the study drug during the treatment phase, and (3) took a prohibited azole antibiotic; (6) taking an HIV protease inhibitor; (7) taking a drug containing cobicistat; (8) diabetic patients taking aliskiren hemifumarate treatment; (9) history of hypersensitivity to olmesartan medoxomil or (10) azelnidipine; (11) pregnant or possibility of becoming pregnant; and (12) judged by the principal investigator or sub-investigator to be ineligible for the study.

Endpoints
Primary Endpoint As primary endpoints, patient and physician satisfaction rates at baseline and at 12 weeks were evaluated. The satisfaction questionnaires for patients and physicians are shown in Figure 2. Both questionnaires consisted of 10 questions (Q1–8 concerned satisfaction and Q9 and Q10 concerned the perception of target BP). The responses to Q1–8 included 5 choices (Strongly agree, Agree, Somewhat agree, Somewhat disagree, and Strongly disagree). “Strongly agree” or “Agree” were considered to indicate satisfaction and the other choices were considered to indicate dissatisfaction.

Secondary Endpoint Home BP, including early morning and evening BP, and clinic BP were evaluated at baseline and at 12 weeks. In addition, patient QOL using the Short Form 12-item health survey (SF-12) and visual analog scales (VAS) were evaluated at baseline and at 12 weeks.

Safety Endpoint Data on adverse events (AEs), serious AEs (SAEs), and adverse drug reactions (ADRs) during the study period were collected. An AE was defined as any unfavorable or unintended sign, symptom, or disease that occurred during the treatment phase.

Figure 4. Patient and physician satisfaction survey results. BP, blood pressure; HT, hypertension.
concomitant medication. Safety endpoints were analyzed in the safety analysis set (SAF), which was defined as the population that included all patients with the exception of those who did not take the study drug.

Summary statistics are expressed as n (%) and mean±SD. Differences in BP levels and SF-12 scores between baseline and 12 weeks were assessed using a paired t-test. Difference in VAS scores between baseline and 12 weeks was assessed using a Wilcoxon signed-rank test. Differences in component ratios for satisfaction and dissatisfaction between patients and physicians were assessed using McNemar’s test. Differences in component ratios of both patient and physician satisfaction and other status between baseline and 12 weeks were assessed using McNemar’s test for patients who have data at both baseline and 12 weeks. Alpha was set at 0.05, 2-sided, without considering multiple significance testing. AEs were coded and categorized according to the Medical Dictionary for Regulatory Activities (MedDRA) system organ class and preferred terms.

The target sample size of 300 was estimated as follows. The difference in the satisfaction rate between physicians and patients was assumed to be 10%. With a 10% difference in the satisfaction rate and using McNemar’s test with a power of 80% (α=0.05, 2-tailed), the required sample size was estimated to be 240 patients. Assuming an approxi-

### Table 2. Changes in Satisfaction Status for Patients and Physicians

| Items                                | Baseline | 12 weeks |
|--------------------------------------|----------|----------|
|                                      | Patient  | Physician | Patient  | Physician |
|                                      | Satisfaction | Dissatisfaction | Satisfaction | Dissatisfaction |
| Q1. Satisfaction with treatment      | 16 (18.8%) | 43 (50.6%) | 53 (65.4%) | 20 (24.7%) |
|                                      | 4 (4.7%) | 22 (25.9%) | 5 (6.2%) | 3 (3.7%) |
| Q2. Involvement in treatment        | 38 (44.7%) | 35 (41.2%) | 53 (65.4%) | 19 (23.5%) |
|                                      | 6 (7.1%) | 6 (7.1%) | 6 (7.4%) | 3 (3.7%) |
| Q3. Understanding of HT             | 36 (42.9%) | 12 (14.3%) | 38 (46.9%) | 16 (19.8%) |
|                                      | 16 (19.1%) | 20 (23.8%) | 16 (19.8%) | 11 (13.6%) |
| Q4. Understanding explanation of HT | 36 (42.9%) | 25 (29.8%) | 41 (50.6%) | 25 (30.9%) |
|                                      | 10 (11.9%) | 13 (15.5%) | 9 (11.1%) | 6 (7.4%) |
| Q5. Reliance                         | 67 (78.8%) | 14 (16.5%) | 67 (78.8%) | 14 (16.5%) |
|                                      | 3 (3.5%) | 1 (1.2%) | 3 (3.5%) | 1 (1.2%) |
| Q6. Antihypertensive drugs           | 16 (18.8%) | 35 (41.2%) | 9 (10.6%) | 25 (29.4%) |
|                                      | 9 (10.6%) | 9 (10.7%) | 6 (7.1%) | 47 (56.0%) |
| Q7. Clinic BP                        | 8 (9.5%) | 27 (32.1%) | 8 (9.5%) | 27 (32.1%) |
|                                      | 5 (6.0%) | 44 (52.4%) | 5 (6.0%) | 44 (52.4%) |

P value: difference in component ratios of satisfaction and dissatisfaction between patients and physicians using McNemar’s test. BP, blood pressure; HT, hypertension.
Patients' Backgrounds

The 116 potential study subjects received a clear explanation of the study and written consent was given by 112 patients (Figure 3). All of these 112 patients were enrolled in the screening phase, and 85 of them were enrolled in the treatment phase; 7 discontinued the study drug, so a total of 78 patients completed the study. The reasons for discontinuation were worsening of complications (n=4), withdrawal of consent (n=1), truancy (n=1), and investigator judgement (n=1). Thus, the FAS, PPS, and SAF were conducted for 85, 78, and 85 patients, respectively. Patients' backgrounds are shown in Table 1. The mean age was 75.3 years old and 49.4% of patients were aged ≥75 years. Complications occurred in 48.2% of patients. Mean early morning BP (SBP/DBP) and evening BP were 157.3/87.2 mmHg and 142.9/78.0 mmHg, respectively. Mean clinic BP was 159.1/80.2 mmHg. By age group, mean SBPs were relatively higher and mean DBPs relatively lower in patients aged ≥75 years compared with patients aged <75 years. In all patients, summary scores for the physical component, the mental component, and the role/social health component using SF-12 were 38.3, 56.7, and 48.5, respectively.

Satisfaction Status

The satisfaction survey results for patients and physicians are shown in Figure 4. Satisfaction rates at baseline were relatively higher in patients compared with physicians for satisfaction for treatment (Q1), with rates of 69.4% vs. 23.5% (patients vs. physicians), involvement in treatment (Q2: 85.9% vs. 51.8%), understanding the explanation of HT (Q4: 72.6% vs. 54.1%), reliance (Q5: 95.3% vs. 82.4%), antihypertensive drug (Q6: 60.0% vs. 29.5%), clinic BP (Q7: 37.0% vs. 17.6%), and home BP (Q8: 41.2% vs. 15.5%). Regarding the perception of target BP (Q9), the rate of patients who answered that they had heard the target BP was relatively lower (52.1%) compared with the rate (92.9%) of physicians who answered that they had informed the patient of the target BP. At 12 weeks of treatment, patient satisfaction rates mainly increased for Q1 (from 69.4% to 90.1%), Q6 (from 60.0% to 76.5%), Q7 (from 37.0% to 68.8%), and Q8 (from 41.2% to 67.5%). The rate of patients who had heard the target BP (Q9) also increased from

Figure 5. Component ratios for both patient and physician satisfaction. P value: difference in component ratios of A and others between baseline and 12 weeks using McNemar's test in patients who had data for both baseline and 12 weeks. BP, blood pressure; HT, hypertension.
52.4% to 71.6% at 12 weeks. Physician satisfaction rates also showed an increase for Q1 (from 23.5% to 71.6%), Q6 (from 29.5% to 65.4%), Q7 (from 17.6% to 54.3%), and Q8 (from 15.5% to 55.5%). Patient and physician satisfaction survey results by age group are shown in Figure S1. Satisfaction rates for clinic BP (Q7) and home BP (Q8) were similar between both age groups, ranging from 34.9% to 47.6% at baseline. Satisfaction rates for understanding (Q9) were relatively lower in patients aged ≥ 75 years compared with the younger (<75 vs. ≥75, Q3: 73.8% vs. 40.5%; Q9: 60.5% vs. 43.9%). However, satisfaction rates for treatment (Q1) at 12 weeks, but at baseline, physicians had been dissatisfied with treatment in 36 (78.4%) of these cases. Similarly, in the 37 cases in which both patients and physicians were satisfied with home BP (Q8) at 12 weeks, in 29 (78.4%) of these cases at baseline, the physicians had been dissatisfied with home BP.

BP
Changes in BP are shown in Table 3. In all patients in the FAS, regarding home BP, the mean early morning BP (SBP/DBP) significantly decreased from 156.4/86.7 mmHg at baseline to 143.3/78.5 mmHg at 12 weeks showing a change of −13.1/−8.2 mmHg (P<0.0001, P<0.0001, respectively). The mean evening BP significantly decreased from 141.7/77.0 mmHg to 130.2/70.1 mmHg, a change of −11.5/−7.0 mmHg (P<0.001, P<0.001, respectively). Mean clinic BP also significantly decreased from 159.2/80.0 mmHg at baseline to 140.4/71.9 mmHg at 12 weeks, with a change of −18.8/−8.2 mmHg (P<0.001, P<0.001, respectively). Significant changes in home and clinic BP rates were also found in both age groups. Concerning medication adherence, a study drug adherence rate ≥80% was found in 82

Table 3. Changes in BP and QOL in a Study of Patient-Physician Concordance

| BP (mmHg), mean±SD | Total | n  | Baseline | 12 weeks | Change | P value |
|-------------------|-------|----|----------|----------|--------|---------|
| **Home BP**       |       |    | 156.4±18.4 | 143.3±16.7 | −13.1±13.2 | <0.0001 |
| Early morning SBP | 70    | 154.4±18.4 | 142.3±16.7 | −12.1±13.2 | <0.0001 |
| Early morning DBP | 70    | 84.7±10.4  | 78.5±9.8 | −6.2±7.3 | <0.0001 |
| Evening SBP       | 70    | 141.7±19.3 | 132.0±15.0 | −9.7±13.7 | <0.0001 |
| Evening DBP       | 70    | 77.0±11.0  | 70.1±9.5 | −6.9±8.1 | <0.0001 |
| **Clinic BP**     |       |    | 140.4±17.7 | 119.4±13.7 | −21.0±10.9 | <0.0001 |
| SBP               | 79    | 159.2±20.1 | 140.4±17.7 | −18.8±20.0 | <0.0001 |
| DBP               | 79    | 80.0±12.0  | 71.9±13.0 | −8.1±10.9 | <0.0001 |
| **QOL**           |       |    | 78.5±19.5 | 75.3±19.5 | −3.2±16.9 | 0.0925 |
| **SF-12 score, mean±SD** |       |    | 38.8±15.9 | 42.1±15.5 | 3.3±16.9 | 0.0925 |
| Physical component summary | 77    | 57.5±9.0  | 56.7±10.2 | −0.8±9.2 | 0.4370 |
| Mental component summary | 77    | 48.2±12.4 | 47.3±10.7 | −1.0±15.1 | 0.5788 |
| Role social health component summary | 78    | 41.5±15.2 | 43.2±15.8 | 1.7±16.0 | 0.3523 |
| Physical functioning | 80    | 42.5±12.7 | 44.0±12.0 | 1.5±13.8 | 0.3040 |
| Role physical      | 80    | 43.5±13.3 | 43.2±13.3 | −0.3±15.5 | 0.8731 |
| Bodily pain        | 78    | 51.2±12.2 | 54.9±11.2 | 3.7±13.6 | 0.0191 |
| General health     | 81    | 55.0±10.0 | 53.3±11.1 | −1.7±10.4 | 0.1520 |
| Vitality           | 81    | 49.9±11.0 | 51.5±9.7 | 1.6±13.9 | 0.3163 |
| Social functioning | 80    | 48.7±10.6 | 48.2±11.2 | −0.5±13.3 | 0.7604 |
| Role-emotional     | 81    | 53.1±9.7  | 52.2±10.3 | −0.9±11.5 | 0.4859 |
| Mental health      | 81    | 71.6±20.7 | 75.3±19.5 | 3.7±20.4 | 0.1214 |
| Happiness status   | 78    | 79.5±20.3 | 81.6±18.9 | 2.1±20.2 | 0.2542 |

P values for BP and SF-12 score: paired t-test; P values for VAS score: Wilcoxon signed-rank test. Abbreviations as in Tables 1,2.
patients, <80% in 2 patients, and unknown for 1 patient.

**QOL**

The QOL scores for the SF-12 and VAS are shown in Table 3. The General health score significantly increased at 12 weeks (P=0.0191) in all patients. No significant change was found in the other items in the SF-12. By age group, the score for happiness status increased significantly between baseline and at 12 weeks (P=0.0191) in all patients. No significant changes were found in the VAS health and happiness scores by age group.

### Table 3: QOL Scores

| Age group | n Baseline | 12 weeks | Change | P value | n Baseline | 12 weeks | Change | P value |
|-----------|------------|----------|--------|---------|------------|----------|--------|---------|
| <75 years |            |          |        |         | ≥75 years  |          |        |         |
| 38        | 151.5±13.0 | 141.2±13.2 | −10.3±11.3 | <0.0001 | 32         | 162.2±22.2 | 145.9±19.9 | −16.3±14.7 | <0.0001 |
| 38        | 89.3±8.7   | 81.7±8.4  | −7.6±6.8 | <0.0001 | 32         | 83.7±11.5  | 74.8±10.1  | −8.9±7.8  | <0.0001 |
| 38        | 137.2±17.4 | 127.8±13.0 | −9.5±14.8 | 0.0004  | 32         | 147.0±20.3 | 133.1±16.8 | −13.9±12.0 | <0.0001 |
| 38        | 78.5±11.1  | 71.7±9.5  | −6.8±9.2 | <0.0001 | 32         | 75.3±10.8  | 68.1±8.5  | −7.2±6.7  | <0.0001 |
| 41        | 152.8±15.7 | 138.3±16.7 | −14.5±17.6 | <0.0001 | 38         | 166.1±22.3 | 142.7±18.6 | −23.4±21.7 | <0.0001 |
| 41        | 83.2±10.6  | 75.5±12.2  | −7.7±10.0 | <0.0001 | 38         | 76.6±12.6  | 68.0±12.8  | −8.6±11.8 | <0.0001 |

- **Safety**

AEs occurred in 4 patients (5 events) with an incidence rate of 4.7%; thoracic vertebral compression fracture (n=1, 1.2%), blood creatinine increase (n=1, 1.2%), BP decrease (n=1, 1.2%), spondylosis deformans (n=1, 1.2%), and headache (n=1, 1.2%). Although the single cases of thoracic vertebral compression fracture and spondylosis deformans were diagnosed as an SAE, no causal relationship with the ARB/CCB combination tablet was found. ADRs occurred in 2 patients (3 events), with an incidence rate of 2.4% and comprising blood creatinine increase (n=1, 1.2%), BP decrease (n=1, 1.2%), and headache (n=1, 1.2%).

**Discussion**

The satisfaction of elderly patients and physicians with HT treatment that addressed concordance was evaluated. Satisfaction rates were relatively higher for patients compared with physicians for most items both at baseline and after treatment; patient satisfaction rates for treatment (Q1), a core item, were 69.4% at baseline and 90.1% after treatment and those for physicians were 23.5% and 71.6%, respectively. Discrepancies in satisfaction between patients and physicians were found at baseline and had improved after treatment. This improvement was related to the increase in physician satisfaction over patient satisfaction. Both home and clinic BP measurements showed a significant decrease after ARB/CCB combination tablet treatment. Patient satisfaction concerning the following showed an increase after treatment: treatment (Q1), antihypertensive drugs (Q6), clinic BP (Q7), and home BP (Q8). Component ratios of both patient and physician satisfaction showed the following significant increases after treatment: treatment (Q1), involvement in treatment (Q2), antihypertensive drugs (Q6), clinic BP (Q7), and home BP (Q8). Results of the SF-12 survey showed the QOL score significantly increased for General health in all patients.

For most survey items, satisfaction rates were relatively higher for patients compared with physicians before and after treatment. One reason for this is the presumed insufficient perception of the target BP in patients, because the rates for perception of target BP (Q9) at baseline were
52.4% in patients and 92.9% in physicians. Another reason may be that home BP monitoring played an important role in patient satisfaction via self-awareness of changes in BP. Yet another reason may be that addressing concordance as an integral part of treatment contributed to patient satisfaction more than to physician satisfaction. Concordance inherently implies a relationship and empathy between patient and physician. Items on the satisfaction survey form were designed with the concept of concordance in mind. Mahmoudian et al reported that patient satisfaction was influenced by the relationship and empathy between patient and physician. Therefore, we presumed that treatment activity, including a survey on satisfaction and QOL, would affect patient satisfaction. Furthermore, an influence of age was also assumed. In the age group analysis for patient satisfaction, although satisfaction rates for clinic and home BP were similar in both age groups at baseline, satisfaction rates for treatment (Q1) and reliance (Q5) were relatively higher in patients aged ≥75 years compared with those <75 years old. These results indicated that patient satisfaction was influenced by factors other than hypotensive effects and that this tendency may become stronger with age.

On the other hand, an essentially important concern is satisfaction based on clinical outcome. In our survey results, satisfaction for treatment (Q1) seemed to be comprehensively reflected in all items; the items mainly showing an increase in rates were patient satisfaction with treatment (Q1), antihypertensive drugs (Q6), clinic BP (Q7), and home BP (Q8), and items that showed increased component ratios for both patient and physician satisfaction were Q1, Q2, Q6, Q7, and Q8. This similarity indicated that control of BP contributed to both the patient’s and the physician’s satisfaction. Furthermore, there were 53 cases showing that both patients and physicians were satisfied with treatment (Q1) at 12 weeks; however, at baseline, 67.9% of the physicians in these cases were dissatisfied with treatment. This finding indicated that physician satisfaction was based on clinical outcome rather than the treatment itself.

Both home and clinic BP measurements showed a significant decrease after ARB/CCB combination tablet treatment. However, the percentage of patients who achieved the target BP level was 32.9% in this study. As reasons why the satisfaction rates were high for achieved target BP levels, the following can be considered. For satisfaction survey items of clinic BP (Q7) and home BP (Q8), both patients and physicians were asked if BP had decreased compared with 3 months earlier (Figure 2). Therefore, the satisfaction rate was considered to reflect the decrease in BP rather than the achievement of the target BP level.

In consideration of all of the above, our results indicated that addressing concordance as part of the treatment improved both patient and physician satisfaction and patient satisfaction was affected not only by BP control but also the patient-physician relationship. Thus, satisfaction surveys for both patients and physicians are necessary to evaluate the influence of concordance on treatment. From this point of view, we think that our results are significant and can be considered as proof of concept of the benefit of designing HT treatment that addresses patient-physician concordance.

The results of the QOL survey showed significant increases in the General health scores in all patients. A previous report showed that the patient-hospital relationship was associated with the QOL of patients. Furthermore, studies of combination drugs for HT showed improved adherence and patient QOL. Chen et al reported that the incidence of AEs ranged from 7.0% to 9.6% in patients receiving antihypertensive drugs, and that patients who had not experienced AEs had higher satisfaction. In the present study, there were relatively low incidence rates for AEs (4.7%) and ADRs (2.4%). Thus, there is a possibility that the efficacy, adherence, study activities, and low incidence of AEs cooperatively contributed to improving the BP control and the General health scores. Regarding the VAS survey, no significant changes were found in the VAS scores for health or happiness in any of the patients. Baseline VAS scores for health and happiness were 70.0 and 78.0, respectively; these relatively high scores may have been a result of the lack of apparent change in all patients.

There have not been reports that include both patient and physician satisfaction rates concerning antihypertensive drug treatment from the viewpoint of concordance. Therefore, we believe this study provides clinically meaningful information on the management of HT in elderly patients.

Study Limitations

This study was a single arm study and there is the possibility that several factors such as the satisfaction survey itself and the use of home BP monitoring affected patient or physician satisfaction. Although the sample size was estimated to be 240 patients, the analysis population was 85 patients, and might have affected the statistical significance test, especially in the results of the QOL survey. However, the number of patients is presumed not to have influenced the trend in the results of the satisfaction survey, which was the primary endpoint of the study. The location of patients taking the survey may constitute a bias concerning satisfaction. A characteristic of the patients in Kagoshima, a provincial city in which residents tend to hold physicians in high esteem, may have affected the satisfaction survey results, especially concerning answers to questions of “reliance”. This study suggested that patient satisfaction was affected by factors other than therapeutic effects and that this tendency may increase with age; further investigation is needed to apply our results to the general HT population, including middle-aged patients. The results of this study need to be interpreted with consideration of the above.

Conclusions

The rates of satisfaction with treatment were relatively higher for patients compared with physicians at baseline. After HT treatment that addressed concordance, both patient and physician satisfaction and the gap in satisfaction between elderly HT patients and physicians showed an improvement.

Conflict of Interest Statement

M.O. has received honoraria from Daiichi Sankyo Co., Ltd, Boehringer Ingelheim, Takeda Pharmaceutical Company Limited, Astellas Pharma Inc., Sumitomo Dainippon Pharma Co., Ltd, Teijin Pharma Limited, Bayer Yakuhin Ltd., Kowa Pharmaceutical Co. Ltd., Otsuka Pharmaceutical Co., Ltd., Kyowa Hakko Kirin Co., Ltd., and Shionogi & Co., Ltd, and research funding and/or scholarship grants from Daiichi Sankyo Co., Ltd, Boehringer Ingelheim, Takeda Pharmaceutical Company Limited, Astellas Pharma Inc., Sumitomo Dainippon Pharma Co., Ltd, Mochida Pharmaceutical Co. Ltd., Actelion Pharmaceuticals Japan, Mitsubishi Tanabe Pharma Corporation, Genzyme Japan, Teijin Home Healthcare, Otsuka Pharmaceutical Co., Ltd., and Bristol-Myers Squibb. The remaining authors declare no conflict of interest.
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Supplementary Files
Supplementary File 1
Figure S1. Patient and physician satisfaction survey results by age group.
Table S1. Changes in satisfaction status of patients and physicians by age group
Table S2. Satisfaction status of patients and physicians at baseline and at 12 weeks
Please find supplementary file(s);
http://dx.doi.org/10.1253/circj.CJ-17-1015