



# Burden of Heart Failure on Patient Daily Life and Patient–Physician Discordance in Disease Management

## — Results From a Cross-Sectional Survey in Japan —

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**Background:** We investigated the impact of heart failure (HF) on daily life and satisfaction with current HF medication from the patient perspective in a real-world study in Japan.

**Methods and Results:** A cross-sectional survey of 154 HF patients treated by 58 cardiologists was conducted in Japan using patient self-completed questionnaires about their daily life and satisfaction with HF medication, as well as patient record forms completed by their physicians capturing corresponding data. The mean age of patients was 72.7 years. The proportion of patients within New York Heart Association Class I, II, III, and IV was 39%, 44%, 16%, and 1%, respectively. Symptoms reported by patients included dyspnea when active (46%), nocturia (43%), anxiety (18%), and depression (6%). There was a discordance between physician- and patient-reported symptoms, especially for nocturia and inability to sleep. The most frequent lifestyle recommendation from physicians was ‘reduce salt/sodium intake’, but only 51% of patients receiving this recommendation followed the advice. In all, 44% of patients reported dissatisfaction with their current medication; according to the patients, 27% reported no discussion with their physicians about their prescribed medication, while physicians reported the opposite.

**Conclusions:** HF negatively impacts patient daily life. There is discordance between patients and physicians in symptom reporting, lifestyle modification advice and adherence, and reported medication decision making. Gaps in patient–physician communication exist.

**Key Words:** Burden; Daily life; Heart failure; Medication; Patient

Heart failure (HF) is a global public health problem affecting an estimated 62 million people worldwide.<sup>1</sup> Epidemiological data show that the incidence of HF is increasing due to aging populations, poor lifestyle practices, and improved survival in individuals who develop HF as the terminal phase of another illness.<sup>2,3</sup> In Japan, the prevalence of and death rates from HF are rising rapidly as a result of the Westernization of lifestyles, particularly dietary changes, and an increasing aging population.<sup>4</sup> The number of HF patients in Japan is estimated to reach 1.3 million by 2035.<sup>5</sup>

HF is a gradually debilitating disease characterized by symptoms such as dyspnea and fatigue,<sup>3</sup> and for many patients the course of HF follows a slow, downward spiral in physical functioning that often results in hospitalization and involuntary dependency on others.<sup>6</sup> Consequently, HF

patients suffer from extensive physical and psychological problems.<sup>7</sup> Overall, quality of life (QoL) deteriorates more profoundly in patients with HF than in those with other chronic diseases.<sup>8</sup>

In Japan, numerous HF registries report on the pathophysiology, epidemiology, and treatment of HF, but mainly from the perspective of physicians and clinical practices,<sup>9–13</sup> and data on life with HF from the patient perspective are limited. Understanding the impact of HF on QoL and satisfaction with medication from the patient perspective, and identifying any discordance between patients and physicians in terms of symptoms and medications, is important for assessing potential unmet needs and improving the treatment of patients with HF. Therefore, the aim of the present study was to investigate the patient-reported burden of HF on daily life, including health-

Received July 1, 2020; revised manuscript received September 9, 2020; accepted September 19, 2020; J-STAGE Advance Publication released online November 17, 2020 Time for primary review: 24 days

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ISSN-2434-0790



Mean ( $\pm$ SD) age (years; n=152)	72.7 $\pm$ 12.4
Age group	
$\leq$ 75 years	79 (52)
$>$ 75 years	73 (48)
Sex (n=154)	
Male	101 (66)
Female	53 (34)
Mean ( $\pm$ SD) BMI (kg/m <sup>2</sup> ; n=139)	22.7 $\pm$ 4.9
Attending an HF program or rehabilitation unit (n=133)	
Yes	13 (10)
No	120 (90)
Current NYHA classification (n=153)	
Class I	60 (39)
Class II	67 (44)
Class III	25 (16)
Class IV	1 (1)
Ejection fraction (n=121)	
$<$ 50% (HF <sub>r</sub> EF)	63 (52)
$\geq$ 50% (HF <sub>p</sub> EF)	58 (48)
Employment status (n=106)	
Working full-time	15 (14)
Working part-time	7 (7)
Homemaker	9 (8)
Student	1 (1)
Retired/pensioner	38 (36)
Unemployed	36 (34)
Marital status (n=149)	
Married/living together	99 (66)
Single	11 (7)
Widowed	30 (20)
Divorced	9 (6)
Living status (n=142)	
Living alone	30 (21)
Living with someone else	112 (79)
Annual household income before tax, including any pensions (n=121)	
No income	13 (11)
$<$ 3,000,000 yen	70 (58)
$\geq$ 3,000,000 to $\leq$ 5,999,999 yen	35 (29)
$\geq$ 6,000,000 yen	3 (3)
Drop in income due to HF-related change in job or reduction of hours (n=35)	9 (26)

Unless indicated otherwise, data are presented as n (%). BMI, body mass index; HF, heart failure; HF<sub>p</sub>EF, heart failure with preserved ejection fraction; HF<sub>r</sub>EF, heart failure with reduced ejection fraction; NYHA, New York Heart Association.

related QoL (HRQoL), and patient satisfaction with HF medication compared with physician perspectives in a real-world setting in Japan.

## Methods

### Study Design

Data were collected from the Adelphi HF Disease Specific Programme™ (DSP),<sup>14</sup> a cross-sectional survey of physicians and their HF patients conducted in a real-world setting in Japan between February and July 2016.<sup>15</sup> The DSP

<b>EQ-5D-3L domain</b>	
EQ-5D: Mobility (n=149)	
I have no problems in walking about	86 (58)
I have some problems in walking about	61 (41)
I am confined to bed	2 (1)
EQ-5D: Self-care (n=147)	
I have no problems with self-care	121 (82)
I have some problems washing or dressing myself	22 (15)
I am unable to wash or dress myself	4 (3)
EQ-5D: Usual activities (n=148)	
I have no problems with performing my usual activities	88 (59)
I have some problems with performing my usual activities	52 (35)
I am unable to perform my usual activities	8 (5)
EQ-5D: Pain/discomfort (n=144)	
I have no pain or discomfort	89 (62)
I have moderate pain or discomfort	53 (37)
I have extreme pain or discomfort	2 (1)
EQ-5D: Anxiety/depression (n=142)	
I am not anxious or depressed	112 (79)
I am moderately anxious or depressed	27 (19)
I am extremely anxious or depressed	3 (2)
<b>Mean (<math>\pm</math>SD) utility score (n=139)</b>	<b>0.8<math>\pm</math>0.2</b>
<b>Mean (<math>\pm</math>SD) EQ-5D VAS (n=129)</b>	<b>67.1<math>\pm</math>19.7</b>

Unless indicated otherwise, data are presented as n (%). EQ-5D VAS, health status score on the day of the interview, scored using a 100-mm visual analogue scale ranging from 0 (worst health you can imagine) to 100 (best health you can imagine).

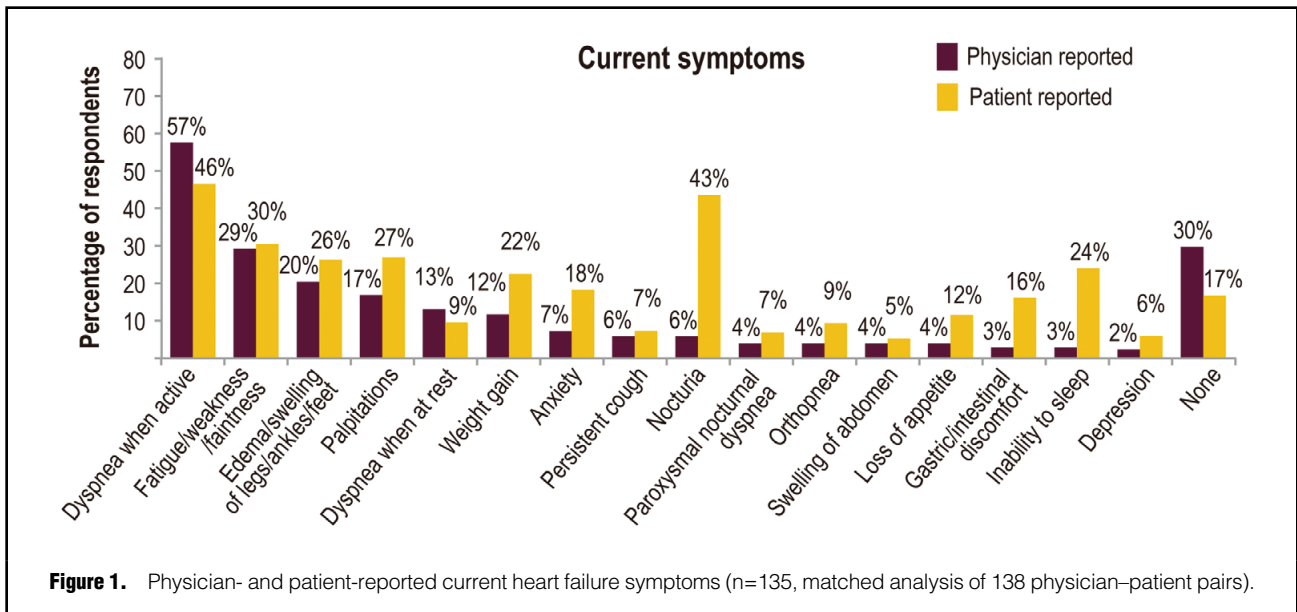
comprises 3 main phases: a preparatory phase involving the development of survey materials and participant recruitment, a data-collection phase, and data analysis. Details of these 3 phases have been described previously.<sup>14</sup>

### Preparatory Phase and Development of Fieldwork Materials

Data were captured prospectively using the following methods: a physician survey, a patient record form (PRF), and a patient self-completion questionnaire (PSC). Physicians were identified from public lists of healthcare providers (HCPs) and invited to participate in the study, provided they had qualified as a cardiologist between 1974 and 2012, consulted with at least 4 patients with HF per week, and were personally responsible for drug treatment decisions. The physician survey was used in face-to-face interviews with cardiologists. PRFs were completed by the cardiologists for patients presenting with HF, using data from medical records. PSCs were completed by patients, whose information was recorded in the PRFs. The questionnaires were developed with input from experts in HF care in English and then translated into Japanese.

### Data-Collection Phase

PRFs were completed by eligible cardiologists who were asked to report information for up to 8 patients (a maximum of 4 patients per physician diagnosed with HF with reduced ejection fraction [HF<sub>r</sub>EF] and a maximum of 4



patients per physician with HF with preserved ejection fraction [HFpEF]). PSCs were completed independently by consenting patients for whom physicians had completed a PRF. PSCs gathered information on patient demographics, lifestyle, HF symptoms, problems and satisfaction with HF medicines, and the impact of HF on HRQoL. Patient HRQoL was evaluated using the 3-level, 5-dimension EuroQoL questionnaire (EQ-5D-3L),<sup>16</sup> which assesses mobility, self-care, usual activities, pain and discomfort, and anxiety and depression. For each dimension, respondents answered on a 3-point scale: no problems, some problems, or extreme problems.<sup>16</sup> Patients were asked to indicate their health status on the day of the interview using a 100-mm visual analogue scale (VAS) as part of the EQ-5D, ranging from 0 (worst health you can imagine) to 100 (best health you can imagine). The EQ-5D was completed at the same time as the PSCs.

The survey was conducted in line with the European Pharmaceutical Market Research Association code<sup>17</sup> and the *US Health Insurance Portability and Accountability Act 1996*,<sup>18</sup> and as such ethics approval was not necessary. Informed consent was obtained from patients by ticking a box on the front page of the questionnaire before data collection.

### Data-Analysis Phase

Basic descriptive statistics were derived using QPSMR Reflect version 2007.1g (QPSMR, Wallingford, UK). Results are presented as the mean±SD or as the number and percentage of responses.

## Results

### Demographics and Clinical Characteristics

In all, 403 PRFs were received from 58 physicians, and 154 patients with a physician-completed PRF completed a PSC and were included in the analysis. Physician characteristics are summarized in **Supplementary Table 1**, while patient demographics and clinical characteristics are summarized in **Table 1**. Mean patient age was 72.7±12.4 years and two-

thirds of patients were male (66%). Using the New York Heart Association (NYHA) classification system, most patients were in Class I or II (39% and 44%, respectively). Overall, 71% and 33% of patients had been diagnosed with HF >1 and >5 years earlier, respectively (**Supplementary Table 2**).

### Impact of HF on HRQoL

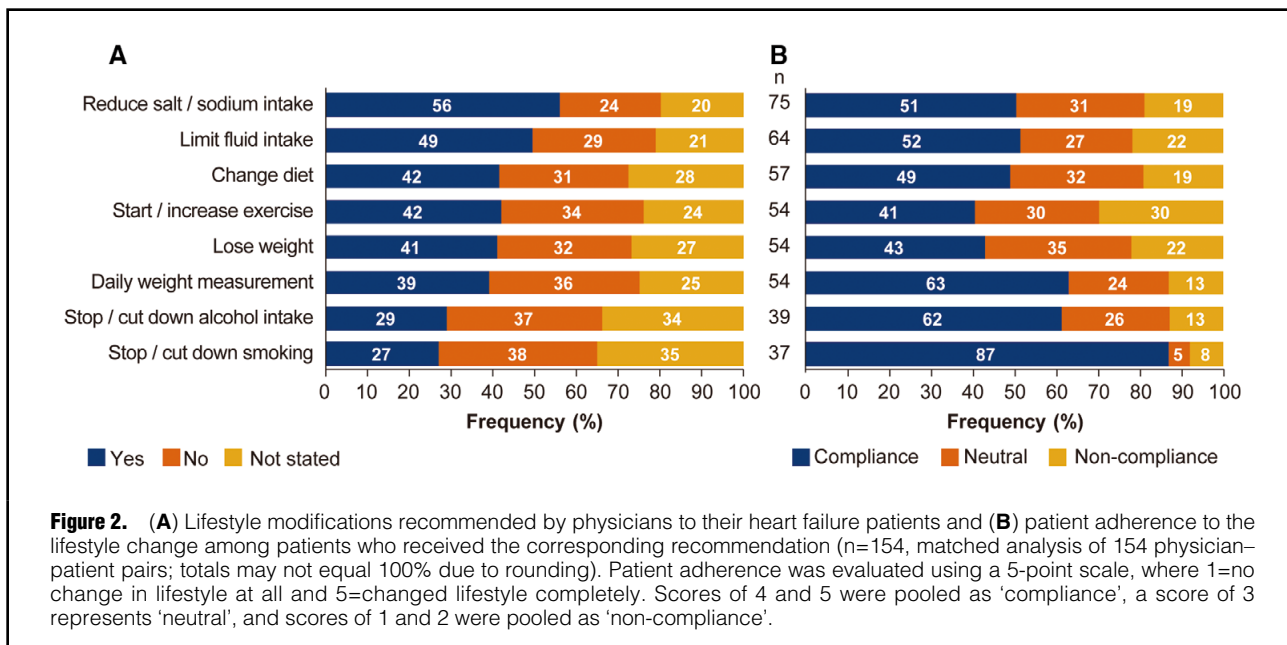
The impact of HF on patient HRQoL, as measured by the EQ-5D-3L completed at the time of the survey, is summarized in **Table 2**. The proportion of patients reporting a moderate or severe impact of HF on their HRQoL in terms of mobility, self-care, and usual physical activities was 42%, 18%, and 40%, respectively. Furthermore, 38% of patients reported experiencing pain or discomfort and 21% of patients reported anxiety or depression. Mean patient-reported health status on the 100-mm EQ-5D VAS was 67.1±19.7.

### Current HR Symptoms

Symptoms currently experienced as reported by matched analysis of 138 physician–patient pairs are shown in **Figure 1**. Dyspnea when active was the most common symptom reported by both patients (46%) and physicians (57%). Nocturia was the second most frequent patient-reported symptom (43%), but was one of the least reported symptoms according to physicians (6%). In addition, patients reported related psychological symptoms, such as anxiety (18%) and/or depression (6%). Except for dyspnea when active, all other symptoms were reported by a higher proportion of patients than physicians.

### Lifestyle Modifications

Lifestyle modifications recommended by physicians to their HF patients are shown in **Figure 2A** and patient adherence rates to physician recommendations are shown in **Figure 2B**. Lifestyle changes most frequently recommended to patients by physicians included limiting salt or sodium intake and limiting fluid intake, which were recommended by 56% and 49% of physicians, respectively



(Figure 2A). In response, approximately half the patients stated that they were compliant in reducing their salt or sodium intake or limiting fluid intake (Figure 2B). Only 27% of physicians recommended patients to stop or cut down on smoking, which was the least frequently recommended lifestyle change; however, most patients (87%) who received this advice stated that they complied.

### Satisfaction With Current HF Medication

Over half the patients were satisfied with their current HF medications (74/132; 56%), whereas 41% (54/132) were dissatisfied with their current HF medications but believed them to be the best treatment or outcome that could be achieved. The remaining 3% of patients were dissatisfied with their current HF medication and did not believe it to be the best available (Figure 3A). Figure 3B summarizes the patient-reported reasons for satisfaction or dissatisfaction with currently prescribed HF medications. The 3 most frequent patient-reported reasons for dissatisfaction with their prescribed HF medication were the cost of medicine (22%), that it was ineffective in reducing the impact of HF on QoL (12%), and being unable to continue work and/or perform their responsibilities (12%). Figure 3C shows patient-reported views on shared decision making about their prescribed HF medication. Just over half the physicians and patients were in agreement regarding the decision-making process for the most recently prescribed treatment, with 36% of patients and physicians agreeing that they discuss all the treatment options but the physician makes the final decision, and 18% of patients and physicians agreeing that the physician makes the decision without any discussion. Discrepancies between physicians and patients regarding shared decision making were observed: although 64% of physicians stated that they made the treatment decision following discussion with their patients, 27% of those patients felt that their physician made the decision without discussing it with them. Further, 47% of patients responded that their physician made the decision about their last prescribed medicines with no discussion, whereas

29% of those physicians stated that they had discussed the treatment option with their patient.

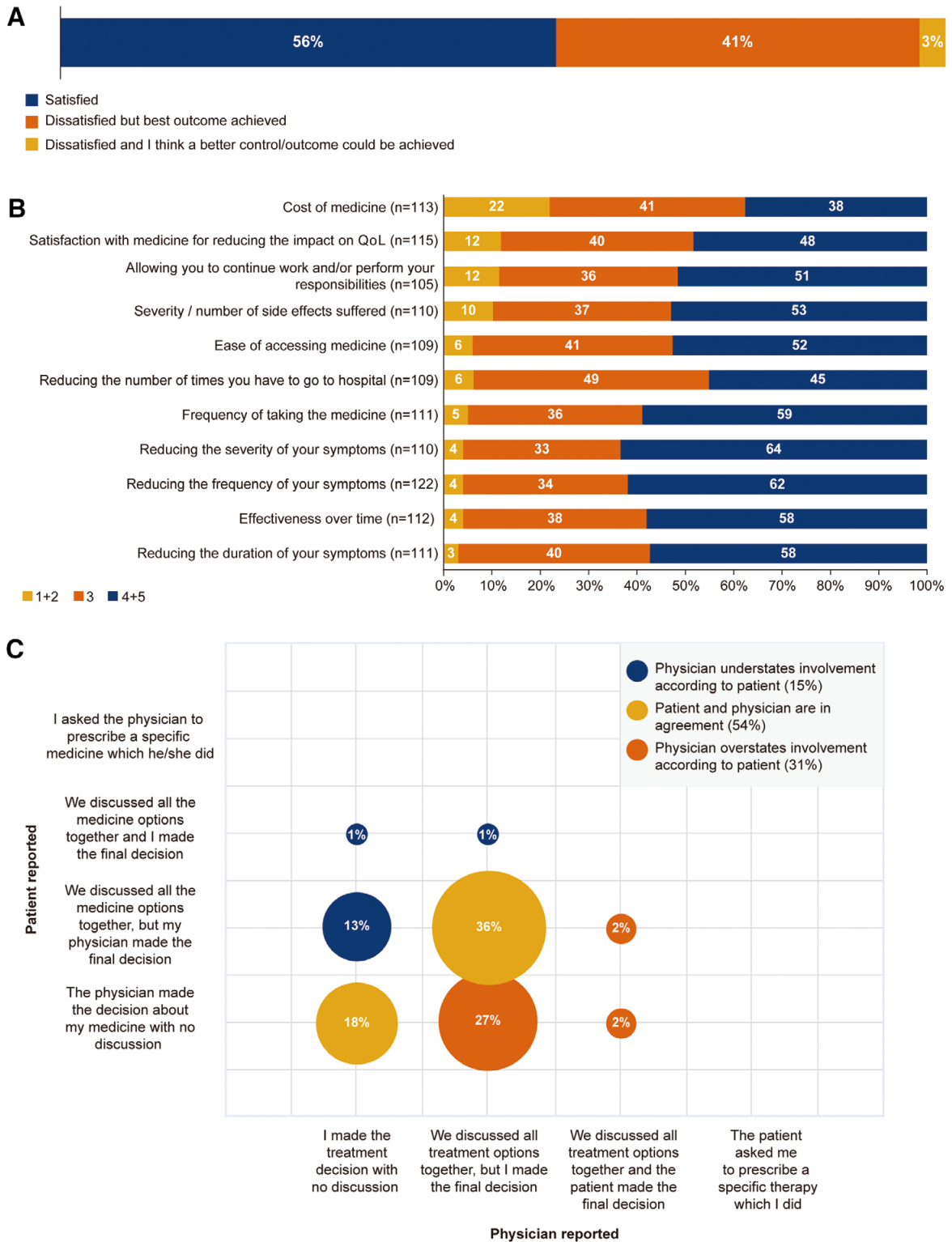
## Discussion

The aim of this cross-sectional survey using the Adelphi DSP was to investigate the patient-reported burden of HF and patient satisfaction with HF medication in a real-world setting in Japan. This study reports gaps between patients and physicians in terms of HF symptoms, lifestyle modifications, and discussion regarding prescribed medications. To the best of our knowledge, this study represents the first of its kind.

### Disease Burden

The results of this study show that HF can exert both a physical and mental burden on patients, including negatively impacting daily activity and triggering anxiety, as well as causing pain and discomfort. These findings are consistent with HF symptoms reported previously by patients with advanced HF.<sup>2</sup> It has also been reported that the prevalence of physical and psychological burden in patients with end-stage HF is of the same level as in cancer patients,<sup>19</sup> and that poor HRQoL in HF patients is associated with increased risk of rehospitalizations and higher mortality rates, as well as reduced patient psychological and social wellbeing.<sup>20</sup> The mean age of patients in this survey was quite high (72.7 years), similar to that in other large-scale observational studies of HF in Japan.<sup>10–12</sup> Considering that older patients often have other comorbidities, which were not surveyed here, we cannot confirm whether the symptoms reported by the patients were related to HF itself or to the patient’s age or the presence of other comorbidities. Future studies should consider such factors in order to identify the burden of HF-based symptoms.

We also found that HF can influence patient employment prospects and, in some cases, lead to a reduction in income. Reflective of the fact that the prevalence of HF increases with age,<sup>5</sup> the number of employed patients was low in the



**Figure 3.** Prescribed heart failure (HF) medications, showing (A) overall patient-reported (dis)satisfaction with currently prescribed HF medications (n=132) and (B) patient-reported reasons for (dis)satisfaction with currently prescribed HF medications. Patient satisfaction was evaluated using a 5-point scale, where 1=extremely dissatisfied and 5=extremely satisfied. Scores of 4 and 5 were pooled as 'satisfied', a score of 3 represents 'neutral', and scores of 1 and 2 were pooled as 'dissatisfied'. QoL, quality of life. (C) Patient perceptions of their input into shared decision making about the HF medications prescribed (n=133, matched analysis of 133 physician-patient pairs).

present study. Nevertheless, one-quarter of patients who answered the question regarding income reported that their income had dropped due to HF-related changes in their job or a reduction in hours, indicating a potential economic burden of HF on patients' lives. In this survey, 48% of patients were >75 years old, 21% of patients lived alone, 69% of patients had an annual household income of <3 million yen, and 11% of patients reported no income. Considering the fact that the average annual income of elderly households in Japan is 3.2 million yen and the average annual income of all households is 5.6 million yen,<sup>21</sup> the annual income of patients in this survey was fairly consistent with the income of elderly people in Japan. However, exploratory investigations of the associations between income and disease burden, or between patient background factors and disease burden, were not performed in the present survey. The population was limited in this study, and further research regarding the economic burden of HF for patients is required.

Despite the burden of disease to patients, there was a discordance between physicians and patients in terms of reporting current symptoms, particularly with regard to nocturia, which was the second most common patient-reported HF symptom (reported by 43% of patients) but reported by only 6% of physicians. There was also discordance in the reporting of the psychological burden of disease, with more patients stating a negative impact of HF on a range of mental health factors compared with their physicians. Given that psychological burden and nocturia are not symptoms that can be confirmed during physical examinations and, instead, are symptoms that need to be reported by the patient, there is likely to be some discordance between the patients and physicians regarding these problems. In a recent nationwide study, 98% of Japanese Circulation Society–authorized cardiology training hospitals reported that palliative care is necessary for HF patients, and demonstrated a correlation between patient care and improved physical and mental symptomatic relief. However, only 42% of institutes offered such care, and most institutions had fewer than 10 cases per year,<sup>22</sup> representing a clear unmet need in the provision of care that may improve symptoms.

### Lifestyle Changes

We also found that despite the impact of HF on patients' daily lives, fewer than half the patients questioned had been advised by their physician to make lifestyle changes to control their disease, and approximately half the patients who were given lifestyle advice did not adhere to the recommendations. This represents both an insufficient level of advice from physicians and a poor level of adherence by patients. Only 10% of patients in this survey responded that they were participating in an HF program or rehabilitation clinic that offered information on HF, exercise, and diet therapy, and emotional, self-care, and medical support (Table 1). Appropriate self-care behaviors play an important role in preventing the worsening of HF, and patient education to improve their self-care capabilities is expected to improve prognosis and QoL.<sup>23</sup> However, multidisciplinary HF care may be lower in an outpatient than inpatient setting, as indicated in the Japan Agency for Medical Research and Development–Congestive Heart Failure (AMED-CHF) study, which demonstrated an implementation rate of 32.6% for outpatients, compared with 78.5% for inpatients.<sup>24</sup> These results and the results of

the present study suggest that multidisciplinary care is important for improving HF and QoL.

### Satisfaction With Medication

The results of this study show that nearly half the patients were not satisfied with their currently prescribed medications and, interestingly, there was a discordance between physicians and patients about the HF medication decision-making process. According to the American Heart Association scientific statement, shared decision making in advanced HF is crucial, particularly as the duration of disease and treatment options have increased.<sup>25</sup> A survey conducted by the American College of Cardiology in 400 patients with HF reported that nearly an equal proportion of physicians (59%) and patients (62%) were in agreement that shared decision making improved the quality of treatment decisions.<sup>26</sup> The mean age of the patients in the current study was 72.7 years and patients' annual household income was comparable to that of the average elderly household in Japan.<sup>21</sup> Meanwhile, 71% of patients had a duration of HF of >1 year. This study did not investigate the relationship between patient income, duration of HF, and satisfaction with HF medications. In the future, it may be necessary to consider the patient's lifestyle and income in the treatment of HF. The Japanese population is aging and the total number of medicines taken increases with age, often resulting in substantial polypharmacy.<sup>27</sup> For patients with HF, who often experience substantial comorbidities, such as hypertension, dyslipidemia, or diabetes,<sup>8</sup> improving treatment satisfaction and the quality of treatment decision making is important. Unfortunately, comorbidities, a history of drug therapy for comorbidities, and the length of the relationship between the physician and patient with respect to HF were not investigated in the present survey, so future studies may need to collect such information when evaluating patients' satisfaction with their medications.

### Addressing Unmet Needs in the Management of HF Patients in Japan: Need for Improved Communication and Social Support

This study identifies clear gaps between patients and physicians in symptom reporting, lifestyle modification recommendations, adherence to recommended lifestyle modifications, and decision making for prescribed HF medications. There was quite high concordance regarding some symptoms, such as fatigue, but marked discordance for others, especially nocturia, sleeplessness, and gastric or intestinal discomfort. It is feasible that patients do not always report these symptoms to their physician, or the physician does not believe these symptoms to be as important or relevant to the diagnosis of HF. There was some discordance in the decision-making process, as shown in Figure 3C, which suggests that the patients and physicians could not always agree as to who had the greatest role in treatment decisions or whether the treatment decisions were made equally. Figure 3C may also suggest that the health literacy of patients was relatively poor, because none of the patients indicated that they asked their physicians to prescribe a specific therapy, relatively few patients made the final treatment decision, and some physicians made the treatment decisions without consulting the patient. Many of these gaps are driven by a lack of communication between physicians and their patients, a situation that is not surprising given the limited physician–patient consultation time often available. Indeed, data from the Japanese Ministry

of Health, Labour and Welfare survey conducted in 2017 showed that consultation time was 5–10 min for approximately 38% of patients and that the consultation time was <5 min in more than 28% of patients.<sup>28</sup> Better and longer communication between patients and their physicians could improve the physical and psychological burden of disease for patients, as well as enabling physicians to better explain lifestyle modifications. It would also enable more time for shared decision making regarding treatment choice. The patient's age, living conditions, and duration of HF may have some impact on these gaps, but factors influencing communication gaps were not explored in the present survey. In addition, poor communication between the physician and patient may also be involved. Although a direct association between patient treatment satisfaction and communication with the physician could not be established from our results, an improvement in communication may help patients to more fully understand their medication and potentially affect their satisfaction with the treatment.

Support and greater communication from other health-care professions beyond the consultation room could provide additional health benefits. Data from the Japanese Kitakawachi Clinical Background and Outcome of Heart Failure (KICKOFF) registry showed that 30% of patients lived alone, that 17% of patients lived with their partner only, and that patients were at risk of social frailty.<sup>29</sup> Patients living alone are anticipated to have the greatest problems in communicating with their physicians.<sup>29</sup> The Japanese Heart Failure Outpatients Disease Management and Cardiac Evaluation (J-HOMECARE) study showed that home-based HF management by nurses who provide symptom monitoring, education, counseling, and telephone follow-up could decrease rehospitalization rates in HF patients and improve their psychological wellbeing.<sup>30</sup> These reports, together with the present study, illustrate the importance of social support for patients and improved communication between patients and both their physician and allied HCPs not only for outpatient consultations, but also for patients at home. Furthermore, given that the prevalence of HF increases with advancing age in Japan,<sup>5,31</sup> it is important for the multidisciplinary team to provide advice to family members and caregivers.

### Study Limitations

There are inevitable limitations in this study that need to be considered when interpreting the findings. First, the study sample size was relatively small; therefore, future studies on larger patient populations are needed to confirm our results. Second, as with any survey or questionnaire, patients may have been limited by the available response options without the possibility for authors to draw other conclusions. Because the PSCs were completed by the patients on a voluntary basis, it is possible that more motivated patients or patients with a better relationship with their HCP were more likely to complete the surveys and that other patients, such as those with a poor relationship with their HCP, were less likely to complete the survey. Other important limitations to consider include recall bias, missing data, and the lack of representativeness of the study sample to the overall HF population. In addition, due to the fact that the selection of patients in this study favored the inclusion of patients who had visited the cardiologists at the time of the study, the data may not be representative of those patients who were not actively consulting physicians or who consult less frequently or

were managed in primary care centers or by other specialties. However, in Japan, cardiologists are the specialists predominantly responsible for the initial consultation, diagnosis, and treatment of HF patients, so from this perspective it is likely that the study findings are representative of current practice in Japan. Unfortunately, information on the length of time the patient was treated by the HCP was not recorded, so we could not examine whether the length of the patient–physician relationship is a contributing factor. One-third of patients were diagnosed with HF >5 years earlier, which may provide sufficient time for a patient–physician relationship to develop. However, we do not know whether the patient was treated by the same physician or multiple physicians since diagnosis, which may contribute to or hinder the development of a patient–physician relationship. It is also possible that there are underlying confounding factors that should be considered, including the patient's age, because some symptoms may be age related or related to other comorbidities. Furthermore, the decision-making process and treatments or interventions may be influenced by the patient's age or the presence of other comorbidities. Nonetheless, the Adelphi DSP methodology is well established, capturing real-world clinical data, behavior, and attitudes of both patients and their physicians across a wide range of disease areas, complementing findings from clinical trials and other studies.<sup>14</sup>

### Conclusions

The present cross-sectional survey of Japanese patients with HF revealed the burden of disease on patient daily life and patient-reported satisfaction with medication. There are gaps between patients and physicians in terms of HF symptoms and discussion over prescribed medications. As the number of HF patients in Japan increases, it is important to reduce the burden of HF on daily life. For this to be achieved, we suggest improvements in communication between patients, caregivers, and family members, and a multidisciplinary team of HCPs.

### Acknowledgments

The authors thank Shweta Vadnerkar of Novartis Pharmaceuticals for providing medical writing support in accordance with the Good Publication Practice (GPP3) guidelines (<http://www.ismpp.org/gpp3>).

### Sources of Funding

This study was funded by Novartis Pharma AG, Basel, Switzerland.

### Disclosures

T.H., Y.M., H. Mitani, H. Murayama, H.K., and N.O. are employees of Novartis Pharma K.K. T.A. has no potential conflicts of interest to declare. R.S. is an employee of Novartis Pharma AG. S.C., J.J., and H.B. are employees of Adelphi Real World. T.A. is a member of *Circulation Reports*' Editorial Team.

### IRB Information

The survey was conducted in line with the European Pharmaceutical Market Research Association code, and the *US Health Insurance Portability and Accountability Act 1996*, and as such ethics approval was not necessary. Informed consent was obtained from patients and physicians before data collection.

### Data Availability

The datasets generated and/or analyzed during the present study are not publicly available because they are proprietary data.

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## Supplementary Files

Please find supplementary file(s);  
<http://dx.doi.org/10.1253/circrep.CR-20-0073>