Evaluation of an Integrated Device Diagnostics Algorithm to Risk Stratify Heart Failure Patients
— Results From the SCAN-HF Study —

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**Background:** Integrated device diagnostics, Triage-HF, is useful in risk stratifying patients with heart failure (HF), but its performance for Japanese patients remains unknown. This is a prospective study of Japanese patients treated with a cardiac resynchronization therapy defibrillator (CRT-D), with a Medtronic OptiVol 2.0 feature.

**Methods and Results:** A total of 320 CRT-D patients were enrolled from 2013 to 2017. All received HF treatment in the prior 12 months. Following enrollment, they were followed every 6 months for 48 months (mean, 22 months). Triage-HF-stratified patients at low, medium and high risk statuses at every 30-day period, and HF-related hospitalization occurring for the subsequent 30 days, were evaluated and repeated. The primary endpoint was to assess Triage-HF performance in predicting HF-related hospitalization risk. All device data were available for 279 of 320 patients (NYHA class II or III in 93%; mean left ventricular ejection fraction, 31%). During a total of 5,977 patient-month follow-ups, 89 HF-related hospitalization occurred in 72 patients. The unadjusted event numbers for Low, Medium and High statuses were 19 (0.7%), 42 (1.6%) and 28 (4.1%), respectively. Relative risk of Medium to Low status was 2.18 (95% CI 1.23–3.85) and 5.78 (95% CI 3.34–10.01) for High to Low status. Common contributing factors among the diagnostics included low activity, OptiVol threshold crossing, and elevated night heart rate.

**Conclusions:** Triage-HF effectively stratified Japanese patients at risk of HF-related hospitalization.

**Key Words:** Heart failure; Hospitalization; Implantable device diagnostics; Risk stratification

With an aging population, heart failure (HF) poses significant clinical and economic burdens in developed parts of the world, including Japan. HF worsening is associated with increased morbidity and mortality, while HF hospitalizations account for a majority of the associated expense,1–3 and each hospitalization event appears to add an incremental amount to a patient’s mortality risk.4 Thus, solutions to proactively identify patients at increased risk of worsening HF to allow for a timely intervention are needed.
Along with guideline-directed medical therapy, implantable cardioverter-defibrillator (ICD) and cardiac resynchronization therapy (CRT) devices have become important tools in the medical repertoire for treating persistent systolic HF.6 In addition to providing life-saving therapies, these devices also have versatile monitoring capabilities. They collect several physiological data on a continuous basis, including patient activity, day and night heart rate (NHR), atrial tachycardia/atrial fibrillation (AT/AF) burden, mean ventricular rate during AT/AF, percent CRT pacing, number of shocks, and intrathoracic impedance and associated index (e.g., OptiVol; Medtronic Inc., MN, USA). Several parameters such as NHR,7 patient activity,7,8 drop in percent CRT pacing,9,10 AT/AF burden and poor rate control,11 and intrathoracic impedance,12 have previously been shown to be associated with worsening HF and mortality risk. Recently, an integrated diagnostics (ID) approach has been developed that combines all available diagnostic parameters into a single metric, referred to as Heart Failure Risk Status or Triage-HF, and improves upon performance of individual parameters.13 The algorithm uses 30 days of device diagnostic data to predict HF hospitalization risk for the next 30 days. The HF risk is categorized as Low, Medium, or High, and the published literatures reported performances of the Triage-HF algorithm in non-Japanese populations.13,14 Its performance in the Japanese HF patients and healthcare system, however, remains unknown. Given that Japanese patients (e.g., demographics) and their healthcare system (e.g., threshold for hospitalization and hospitalization duration) are different from Western medical systems, the reported performance of the ID algorithm may not be translatable to the Japanese setting. To resolve this question, we conducted the prospective, multicenter Risk Stratification by IntegrAted DiagnNostics in Patients With Heart Failure (SCAN-HF) study, aiming to characterize the performance of the ID algorithm in the Japanese HF patient population.

Methods

The SCAN-HF study was a prospective, non-randomized, post-market, multi-center observational study that was conducted at 20 Japanese institutions between March 2013 and June 2017. The protocol of the study was reviewed and approved by the Ethics Committee at each institution. All patients gave written informed consent before the enrollment in the study (Clinical Trials: SCAN-HF study, UMIN000009522).

Study Subjects

Adult HF patients (aged ≥20 years) with an existing or a newly implanted CRT-D device with OptiVol 2.0 feature (Medtronic Inc.) were considered for enrollment in the study. Eligible patients were required to have a HF-related hospitalization or an outpatient visit with documented intervention for treating HF exacerbation (e.g., treatment with diuretics, vasodilators or inotropes) within the previous 12 months. The study protocol required at least 15 months of follow-up after enrollment. Also, patients with short life expectancy (<15 months) or those who were participating in a different study (or were intending to participate) were excluded from the study. After the enrollment, all patients were followed up in the participating clinic at 6, 12, 15, 18, 24, 30, 36, 42 and 48 months. All of the device diagnostic data were collected by using onsite device interrogation during each clinic visit, and were used for the calculation of HF risk status.

Characterization of Triage-HF Performance

The primary objective of the study was to assess the performance of Triage-HF in the Japanese CRT-D patient population. The details of the Triage-HF algorithm have been reported previously.13 Briefly, the algorithm assumed a baseline probability of HF hospitalization in the HF population to be 10% over 6 months. Each of the device variables, including intrathoracic impedance, patient activity, NHR, heart rate variability, percent pacing, AT/AF burden, ventricular rate during AT/AF, and detected arrhythmia episodes/shocks delivered, were assigned to discrete states wherein the higher state was associated with a greater likelihood of HF event.13 These assigned variable states were then used to generate a risk score from 0 to 100% using a Bayesian Belief Network model. The cut-offs were then drawn on this score to stratify patients in Low- (score <5%), Medium- (score ≥5% and <20%) and High-risk categories (score ≥20%). Risk status at a given time point is assessed using the previous 30 days of device data and predicts risk of an event happening for the subsequent 30 days (Figure 1). Thus, in the same patient, a 30-day assessment of the risk (Low or Medium or High) was repeatedly performed during the follow-up period.

We sought to characterize the rate of HF hospitalization events for Triage-HF derived Low-, Medium- and High-risk statuses. The event was defined as HF-related if it required therapeutic intervention using either of the following measures during hospitalization: oral or non-oral diuretics, vasodilators and inotropes, or another non-oral HF medication. All events were reviewed and adjudicated by an independent endpoint adjudication committee consisting of 3 physicians with HF expertise. Further, we characterized device diagnostic parameters that contributed to elevated risk for HF-related hospitalizations.
an event and the relative risk along with 95% confidence intervals. This model was used to account for the multiple monthly evaluations in each subject. The Kaplan-Meier method was used to compute the event-free survival curves. All statistical analyses were performed using SAS version 9.4 (SAS Institute, Inc. Cary, NC, USA), and a P value of <0.05 was considered significant.

### Results

#### Patient Demographics

A total of 320 patients were enrolled in the study. The mean follow-up period was 22±12 months. Of 320 enrolled patients, 5 patients did not meet the inclusion/exclusion criteria and were hence excluded. The device diagnostics data necessary for computing the risk status were available from 279 patients, and this cohort was used for the Triage-HF performance analysis. Table 1 summarizes clinical and demographic characteristics for 315 patients who met all inclusion/exclusion criteria and were fully enrolled in the study. The mean age was 68.3±11.9 years and 69.8% were male. Consistent with the device implantation indications, a majority (93%) of the patients were diagnosed as NYHA II and NYHA III heart failure. The mean ejection fraction was 30.7±10.8%. The patients were managed by the physician at each institution regarding administration of β-blockers, angiotensin-converting enzyme inhibitor, angiotensin receptor blocker, diuretics, and mineralocorticoid receptor antagonist.

#### Performance of Triage-HF

Table 2 shows the performance of Triage-HF in 279 patients in whom complete device data were available. During the total of 5,977 patient-month follow-ups, 89 HF-related events (hospitalization) occurred in 72 patients. The unadjusted event numbers (incidences) for Low-, Medium- and High-risk statuses for a 30-day period were 19 (0.7%) in 17 patients, 42 (1.6%) in 31 patients and 28 (4.1%) in 24 patients, respectively. GEE-adjusted event rates did not differ significantly from the unadjusted event rates (Table 2). As Triage-HF was dynamically evaluated using 30 days of device diagnostic data at a time, a given patient could contribute to more than one risk status (Figure 1; e.g., a patient can be in Low status during month 1 and then move to High-risk status during month 6). Thus, High-risk status had a 5.78-fold higher relative risk of a HF event in the next 30 days than Low risk in the next 30 days. The relative risk of Medium- vs. Low-risk status was 2.18-fold. Table 3 shows sensitivity, specificity, and positive and negative predictive values of High-risk status vs. Medium- and Low-risk statuses, and those of High- and Medium-risk statuses vs. Low-risk status. The positive

### Data Analysis

All data are shown as mean±1 standard deviation. In this study, monthly evaluations were included in the analysis if there were 30 days of device diagnostic data available before the evaluation and 30 days of follow-up data available after the monthly evaluation. A generalized estimating equations model (GEE) was used to estimate the risk for

| Risk status | Number of patients | Number of patient month (%) | Number of events (%) [number of subjects with an event] | GEE estimate (95% CI) | Relative risk estimate (95% CI) |
|-------------|-------------------|-----------------------------|--------------------------------------------------------|-----------------------|---------------------------------|
| Low         | 239               | 2,631 (44)                  | 19 (0.7) [17]                                           | 0.73 (0.45, 1.17)     | Ref.                             |
| Medium      | 268               | 2,668 (45)                  | 42 (1.6) [31]                                           | 1.57 (1.09, 2.26)     | 2.18 (1.23–3.85)                 |
| High        | 161               | 678 (11)                    | 28 (4.1) [24]                                           | 4.07 (2.82, 5.84)     | 5.78 (3.34–10.01)                |

CI, confidence interval; GEE, generalized estimating equations model; HF, heart failure.
and negative predictive values of High- vs. Medium- and Low-risk status were 4.1% and 98.8%, respectively. Those of High- and Medium- vs. Low-risk status were 2.1% and 99.3%, respectively.

**Figure 2** shows the Kaplan-Meier survival curves for the three risk groups. The proportion of patients who remained event-free during the 30-day duration of post risk assessment decreased for Medium- and High-risk groups relative to the Low-risk group.

**Table 4** shows the device diagnostic parameters that contributed to each of the risk categories. The bottom portion of the table shows the proportion of the total n for each risk category with various numbers of risk factors. For the High- and Medium-risk statuses, low activity was the most frequently triggered risk factor (96.4% and 57.1%, respectively). This was followed by OptiVol and elevated NHR. Low risk occurred with, at most, one risk factor, and in general, the number of triggered risk factors increased for Medium- and High-risk statuses. Medium-risk status required 1, 2 or 3 risk factors, whereas the number of risk factors triggered for High-risk status ranged from 2 to 6. A vast majority (82.15%) of High-risk status occurrences had 2–3 risk factors.

We assessed the performance of Triage-HF for HR-related hospitalization separately in patient groups with ischemic and non-ischemic cardiomyopathy. In ischemic cardiomyopathy, GEE-adjusted event rates for Low-, Medium- and High-risk statuses were 0.36, 2.18 and 5.99, respectively.
respectively, and the relative risk to Low status was 6.24 in Medium and 17.87 in High status (Table 5). In non-ischemic cardiomyopathy, GEE-adjusted event rates for Low, Medium and High were 0.92, 1.22 and 3.12, respectively, and relative risk of Medium vs. Low was 1.33 and High vs. Low was 3.47 in High (Table 6).

### Discussion

In this study, we presented the performance of the Triage-HF algorithm in a Japanese HF patient population with CRT-D devices. Triage-HF integrates all the device diagnostics data for a 30-day window prior to an evaluation time point into a single metric and stratifies the patient’s risk for a HF event in the next 30 days as Low, Medium or High status. We showed that Triage-HF effectively stratified the Japanese CRT-D patients at risk of HF events, and that the performance of Triage-HF was consistent with that reported previously for non-Japanese patients.\(^\text{13-15}\) We believe this is the first report on the performance of the Triage-HF algorithm in the Japanese patient population.

Previously, several studies have reported the performance of Triage-HF for HF-related cardiovascular events.\(^\text{13-15}\) and that the 30-day HF-related event rates for the High-risk status have been shown to be in the range of 2.61–6.8%. Gula et al\(^\text{14}\) analyzed the algorithm’s performance in a patient population from the RAFT trial,\(^\text{16}\) and their event rate for High-risk status (2.61%) was slightly lower than that shown previously by other studies. This was attributed to a larger proportion of NYHA class II patients in the RAFT trial than those included in previous reports.\(^\text{13,14}\) Similarly, somewhat lower rates of HF-related hospitalization in the present study (4.1%), compared to those previously reported,\(^\text{13,15}\) is likely because of a higher proportion of NYHA class II patients. Thus, the effectiveness of Triage-HF in HF risk stratification and particularly the event rates in Medium- and High-risk groups depend on the baseline severity of HF status of the study patients. The fact that incidence of HF and treatment strategies (e.g., criteria for patient hospitalization) can vary among different healthcare systems in different countries means that algorithm performance may also vary. Thus, our study fills an important gap by characterizing the performance of the Triage-HF algorithm in the Japanese patient population.

The fact that the presence of multiple risk factors in device diagnostics data enhances overall specificity of identifying a HF event is not surprising given that various parameters are reflective of different underlying physiological processes. As a result, they likely provide orthogonal information, which when combined improves the overall performance of the combinatorial approach. For example, impedance is an indicator of fluid status,\(^\text{12}\) while elevated NHR and low HRV are potential markers of imbalance in autonomic tone. Lower activity can be a signal of compromised functional capacity.

Triage-HF uses all-existing device diagnostic parameters as input. Thus, in principle, all the necessary information for triaging patients is already available to clinicians. In fact, clinicians can use published thresholds of various device diagnostic parameters in a PARTENERS\(^\text{17}\) like scheme to triage high-risk patients. However, the manual review of device diagnostic data to extract risk-bearing features can be tedious and cumbersome. Triage-HF facilitates this process and makes device data review more efficient by summarizing risk factors in an easy-to-understand format. Its usefulness has been validated by the prospective Canadian TRIAGE-HF study, showing that High-risk status has a good predictive accuracy for patient-reported signs, symptoms, and behaviors associated with worsening HF status.\(^\text{18}\) A recent real-world clinical study revealed that a combination of the assessment of Triage HF via the remote monitoring system and a simple telephone review when High-risk status is reported offers a feasible and clinically useful monitoring tool for HF patients with cardiac implantable electronic devices.\(^\text{19}\)

We demonstrated that the number of contributing factors typically increased with increasing risk status (Table 4).

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### Table 5. Performance of Triage-HF for Stratifying Patients at the Risk of HF-Related Hospitalization in Ischemic Cardiomyopathy

| Risk status | Number of patients | Number of patient month (%) | Number of events (%) [number of subjects with an event] | GEE estimate (95% CI) | Relative risk estimate (95% CI) |
|-------------|--------------------|-----------------------------|--------------------------------------------------------|-----------------------|-------------------------------|
| Low         | 49                 | 560 (41)                    | 2 (0.4) [2]                                            | 0.36 (0.09, 1.39)     | Ref.                          |
| Medium      | 268                | 594 (44)                    | 13 (2.2) [8]                                           | 2.18 (1.06, 4.42)     | 6.24 (1.31–29.83)             |
| High        | 36                 | 203 (15)                    | 12 (5.9) [9]                                           | 5.99 (3.48, 10.10)    | 17.87 (4.04–78.96)            |

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### Table 6. Performance of Triage-HF for Stratifying Patients at the Risk of HF-Related Hospitalization in Non-Ischemic Cardiomyopathy

| Risk status | Number of patients | Number of patient month (%) | Number of events (%) [number of subjects with an event] | GEE estimate (95% CI) | Relative risk estimate (95% CI) |
|-------------|--------------------|-----------------------------|--------------------------------------------------------|-----------------------|-------------------------------|
| Low         | 143                | 1,556 (45)                  | 14 (0.9) [12]                                          | 0.92 (0.52, 1.61)     | Ref.                          |
| Medium      | 156                | 1,560 (45)                  | 19 (1.2) [15]                                          | 1.22 (0.73, 2.04)     | 1.33 (0.67–2.67)             |
| High        | 99                 | 370 (11)                    | 12 (3.2) [11]                                          | 3.12 (1.75, 5.49)     | 3.47 (1.81–6.65)             |

CI, confidence interval; GEE, generalized estimating equations model; HF, heart failure.
For HF-related hospitalization, low activity was the most commonly triggered diagnostic parameter; however, low activity is a non-specific marker of worsening health and hence must be put in context by including other device diagnostic parameters and patient-reported physical conditions. OptiVol was the second most commonly triggered contributing factors, and when present, likely points to volume accumulation. Elevated NHR was also a commonly triggered factor and suggests elevation of sympathetic tone, perhaps secondary to volume accumulation. Although contributing factors can help to lend some insights into mechanisms of worsening patients status, a complete picture of the patient health and necessary intervention is only possible by collecting additional patient information such a patient signs and symptoms and laboratory work-up.

Study Limitations
SCAN-HF was an observational study in a specific patient population (Japanese patients). Thus, the performance of the present Triage-HF may not be extrapolated to other patient populations. In addition, an effective risk stratification by Triage-HF cannot be equated to improvement in patient outcomes. Any data of intervention or treatment added or changed during the follow-up period or after the occurrence of HF-related events were not collected in this study. We therefore could not assess the effect of treatment on the risk status. For those, Triage-HF usage must be combined with an appropriate patient intervention, which remains a subject of future investigation.

Conclusions
The Triage-HF algorithm effectively stratified HF patients with an implantable CRT-D device for risk of HF-related hospitalization in a Japanese patient population.

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