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Title: Concurrent validity and prognostic utility of the Needs Assessment Tool: Progressive Disease Heart Failure.

Running title: Validity of the NAT:PD-Heart Failure

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Title: Concurrent validity and prognostic utility of the Needs Assessment Tool: Progressive Disease Heart Failure

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Abstract

Context: People with advanced heart failure have supportive and palliative needs requiring systematic assessment.

Objectives: We aimed to assess the validity of the Needs Assessment Tool: Progressive Disease – Heart Failure (NAT:PD-HF).

Methods: Secondary analysis of routinely collected patient data from a specialist palliative care-heart disease service improvement project. NAT:PD-HF, the Integrated Palliative care Outcome Scale (IPOS), and patient/carer-report data were collected. Concurrent validity between NAT:PD-HF items and comparison measures (Kendall's tau; kappa); construct validity via known-group comparisons; predictive utility of NAT:PD-HF for survival (multivariable Cox hazard regression model).

Results: Data from 88 patients (50% men; mean age 85; median survival 205 days; 64% left ventricular systolic dysfunction) were analyzed. Prevalence- and bias-adjusted kappa values indicated moderate agreement for physical symptom needs (k: 0.33 for patients, 0.42 for carers). Substantial agreement was observed for patient/carer psychological symptoms, and information needs (k ≥ 0.6). NAT:PD-HF distinguished between patients with different survival, comorbidities, functional scores, and palliative Phase of Illness with moderate to high effect sizes. NAT did not predict survival when adjusted for mortality risk score and functional status (2+ needs HR: 1.52, 95% CI: 1.01-1.74).

Conclusion: The NAT:PD-HF is a valid tool for clinician assessment of physical, psychosocial, and information patient/carer needs.

Keywords: Needs assessment; heart failure; NAT:PD-HF; construct validity

Key message: (word count: 50/50)

Systematic assessment of unmet needs is essential for patient-centred care. In this retrospective cohort study, we show that the NAT:PD-HF, a needs assessment tool for heart failure, validly identifies unmet needs relevant for integrated palliative care. This clinician-based tool can therefore help to triage clinical action for nurses and practitioners.

Introduction

People with advanced heart failure have a significant symptom burden and other concerns, affecting patients and family carers.(1,2) Palliative care and advance care planning can help alleviate these challenges alongside ongoing appropriate active heart failure care to improve quality of life.(1,2) Clinical guidelines recommend access to palliative care according to need.(3-5) Despite this, access to palliative care remains mostly dependent on local clinical champions, with many eligible patients still not receiving timely help, often living and dying with poorly controlled symptoms and unaddressed concerns.(6,7)

A prognostic-based approach to identifying those who may benefit has proved disappointing, missing many who have a significant burden of palliative care needs for many months, and even years.(5) A systematic needs-based approach is needed but few validated tools exist to help clinicians in practice.(8) A recent systematic review suggested that the most promising tool available to date was the Needs Assessment Tool: Progressive Disease – Heart Failure (NAT:PD-HF)[1].(9) The NAT:PD-HF (9) is adapted from the NAT:PD-Cancer tool (10) and includes four sections with 20 items, including the physical and psychosocial needs of the patient and the caregiver/family member. It is a clinician consultation guide rather than an outcome measure, and has undergone preliminary psychometric testing showing promising acceptability, reliability and construct validity,(9,10) and has been identified as the most appropriate clinician-rated needs assessment tool for people with heart failure from evidence so far.(11)

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[1] **Abbreviations**: ADL: activities of daily living, AKPS: Australia-modified Karnofsky Performance Status, COSMIN: Consensus-based standards for the selection of health measurement instruments, GP: general practitioner, GSF: Gold Standards Framework, HADS: Hospital Anxiety and Depression Scale, HR: hazard ratio, ILD: interstitial lung disease, IPOS: Integrated Palliative care Outcome scale, k: kappa, M: mean, MAGGIC: Meta-analysis Global Group in Chronic Heart Failure risk score, max: Maximum, min: Minimum, n: sample size, NAT: Needs Assessment Tool, NAT:PD-HF: Needs Assessment Tool: Progressive Disease – Heart Failure, PABAK: prevalence- and bias-adjusted kappa, SD: standard deviation, Zarit-6: Zarit Caregiver Burden Interview – Short Form 6

We aimed to examine the construct validity and prognostic utility of the NAT:PD-HF using routinely collected data from people with advanced heart failure referred to a clinical service improvement project.

Methods

Patient population & data collection

This retrospective cohort study is a secondary analysis of an anonymised dataset of routinely collected data from a population of patients with advanced heart failure attending a palliative-cardiology service improvement project at St Christopher's Hospice, London. All heart failure patients included in this specialist palliative care clinic were included in the study and analysed. NHS ethics approval was not required. Institutional ethics approval was granted for the secondary data analysis by the Hull Medical School Research Ethics Committee prior to analysis, and data-sharing permission was granted from the data custodian at St Christopher's Hospice. The investigation conforms with the principles outlined in the Declaration of Helsinki.(12)

Clinical, demographic and patient-report data were collected at baseline, with some patient/carer-report data collected at the end of the episode of care, along with service use and information regarding time from referral to death and place of death (see Table 1). The Meta-analysis Global Group in Chronic Heart Failure risk score (MAGGIC) risk score was calculated at baseline. Mortality was assessed *via* medical records at the end of the follow-up period (censored at 20/08/2020).

Patient and carer-report measures for concurrent validity testing included the Integrated Palliative care Outcome Scale (IPOS), Australia-modified Karnofsky Status (AKPS), the Zarit Caregiver Burden Interview 6-item short form, and the Hospital Anxiety and Depression Scale (HADS) (see Table 1). Comparators were chosen on the basis of overlapping constructs by the research team. The IPOS physical summary scale was chosen for the physical NAT:PD-HF item 2.1, but single IPOS items used elsewhere. The HADS anxiety and depression subscales were used. In view of poor construct overlap for individual items in the Zarit-6, only the summary score was used.

Our objective was to explore the concurrent validity between items on the NAT:PD-HF and comparison measures, with the physical subscale as the primary endpoint for comparison and psychological, practical, spiritual, carer strain and information needs as secondary endpoints. We also explored known-group comparisons regarding demographic and clinical characteristics and the MAGGIC score, and investigated the NAT:PD-HF's and other predictors' prognostic utility in predicting time to death. For assessing prognostic utility, time to death (all-cause mortality) in days was the primary outcome.

[Please insert Table 1 about here]

Statistical analysis

Data were analysed using SPSS v26 and Stata v16.1. Descriptive statistics as per data type were used to identify distributions and missing data. Guidelines by the Consensus-based standards for the selection of health measurement instruments (COSMIN) group were followed regarding the validation of clinical measurement tools.(20) To assess concurrent validity between NAT:PD-HF items and comparison measures, Cohen's kappa, prevalence- and bias-adjusted kappa (PABAK) statistic were used. Kendall's tau-b correlation coefficient was calculated to determine the correlation between respective items and constructs. Conceptually, the NAT:PD-HF and the IPOS show the best overlap regarding the physical symptoms subscale.

To support the primary aim of establishing the concurrent validity, the analysis was undertaken on a sample of sufficient power to detect a moderate agreement between the NAT:PD-HF 2.1 and the physical symptoms subscale of the IPOS with a weighted Cohen's kappa of 0.55 and a lower bound for the agreement at $\kappa = 0.30$ with $\alpha = 0.05$ and power = 0.80.

For construct validation, *a priori* hypotheses for known-group comparisons were tested for time of referral to death, palliative Phase of Illness, MAGGIC score and number of comorbidities. Hypotheses tests were Bonferroni-corrected for multiple testing. The prognostic utility of the NAT:PD-HF was tested in a multivariable Cox regression model with proportional hazards. Univariable analysis was performed for the dichotomised NAT:PD-HF score alone. Regarding the sample size, two known likely predictors AKPS and MAGGIC scores were chosen for the multiple model. Multiple imputation was used to impute missing data when needed. (21,22) The hazard ratio (HR) with 95% confidence intervals was calculated for each parameter. The Kaplan-Meier method was used to estimate survival time and produce a survival curve.(23)

Results

Participants

Eighty-eight patients with a mean age of 85 years (SD: 9.6, range: 53-100), 50% male, and a mean length of survival of 276 days (SD: 286, range: 0-958) took part. Patients presented with a number of cardiac conditions and often with more than one cardiac problem. Fifty-six patients presented with heart failure with reduced ejection fraction (64%), 18 with heart failure with normal ejection fraction (20%), 13 with valvular disease (15%), and other (n = 1, 1%). Fifty-nine patients also had arrhythmic heart disease (67%), 45 ischemic heart disease (51%), and nine had cardiomyopathy (10%). Seventy-seven patients (87.5%) had a MAGGIC score indicating a risk of dying in 1 year. Just over a fifth (n=19; 21.6%) had chronic kidney disease stage 4 or 5. The median number of comorbidities was two (range: 0-5). Details of characteristics are shown in Table 2.

The second assessment was made at a median of 182 days after the first assessment (min: 3 days, max: 469 days).

[Please insert Table 2 about here]

Distribution of NAT:PD-HF and self-report measures

Supplementary Table 1 shows the prevalence and distribution of the NAT:PD-HF scores. Data completion was high, with missing responses highest in the carer sections (8% to 9.2% per item) and lowest in Section 2 (Patient Wellbeing) (2.2% to 3.4% per item). All patients were considered to have persistent physical problems (81.4%) of which 79.5% were of significant concern. Clinicians had significant concerns about nearly three-quarters (71.6%) of patients' ability to manage daily living activities. Fewer concerns related to existential concerns (only in 5.7%) or financial/legal matters (25%). Nearly all (93.2%) patients were considered to need further information compared with only a quarter of carers (27.2%).

Other self- and carer-reported measures (Supplementary Table 2) in the sample included the IPOS at baseline and at the end of service delivery, the HADS anxiety and depression scores as well as the Zarit-6 sum score. Descriptive statistics show that the sample presented with a high overall symptom and supportive needs burden of M = 21.5 (SD: 8.9, n = 71) on the IPOS at baseline. The mean IPOS sum score reduced to M = 19.8 (SD: 9.5, n = 61) over the course of treatment by the service. The mean HADS depression score was 7.5 (SD: 3.9), the mean HADS anxiety score was 6.6 (SD: 4.6), with one third of patients demonstrating at least moderate depression scores (30.1%) and 27% demonstrating at least moderate anxiety scores. The mean Zarit-6 sum score of nine (SD: 5) indicated a mild to moderate caregiver burden on average.

Concurrent validity

The primary outcome NAT:PD-HF 2.1 “Patient physical symptoms” showed a statistically significant correlation with the IPOS physical symptoms subscale in the fair range (τ=0.26, p=0.007). Further statistically significant correlations in the small to moderate range were found for NAT:PD-HF item 2.2 “Patient needs regarding activities of daily living” and the Australia-modified Performance Scale score (τ=-0.41, p<0.001), NAT:PD-HF 2.3 “Patient psychological symptoms” and HADS anxiety subscale score (τ=0.27, p=0.017), and NAT:PD-HF 4.1 Caregiver multidimensional problems and Zarit-6 sum score (τ=0.40, p<0.001).

Agreement between NAT:PD-HF concerns and comparator outcomes is shown in Table 3 and as a Figure in Supplemental appendix Figure 1. For the primary outcome, NAT:PD-HF 2.1 Patient physical symptoms, a PABAK value of 0.33 (95% CI: 0.11-0.54) was observed. Six comparisons achieved substantial agreement, seven moderate, and seven (mostly for the carer items) reached fair agreement. The best agreement was found in the areas of patient wellbeing (especially activities of daily living (ADL) [NAT:PD-HF 2.2 and AKPS] and psychological concerns [NAT:PD-HF 2.3 and HADS Anxiety]), and financial/legal (comparison IPOS question 9) and information needs (comparison IPOS question 8) for both patient and carer.

[Please insert Table 3 about here]

In terms of agreement between NAT:PD-HF and other measures, the Zarit-6 sum score demonstrates only a fair agreement; HADS anxiety score and IPOS items 8 & 9 (Information needs & Practical problems) demonstrate a strong agreement; and all other measures achieved a moderate agreement. There were no corresponding measures for NAT:PD-HF items 2.7, 3.4 & 4.2.

Construct validity and prognostic utility of the NAT:PD-HF

In terms of known-groups comparison, five items of the NAT:PD-HF were chosen to be compared according to the demographic variables age, gender, and the clinical variables time from referral to death (in days), MAGGIC score, number of comorbidities, AKPS and palliative Phase of Illness. Of those variables, only time from referral to death, number of comorbidities, AKPS, and phase of illness demonstrated effects in distinguishing between different amounts of needs as measured per NAT:PD-HF item. Time referral to death was differently distributed in needs categories for 2.1 Symptoms needs, 2.2 ADL needs, and 2.8 Information needs. All effects were in the moderate to large range. Number of comorbidities distinguished between NAT needs categories on item 2.3 Psychological needs with a moderate effect size (*d* = 0.57).(24) AKPS showed moderate effects in distinguishing between needs categories for NAT items 2.2 ADL needs , 2.4 Treatment needs, and 2.8 Information needs. Finally, palliative Phase of Illness showed consistently large effect sizes for distinguishing between needs categories for NAT items 2.1 Symptoms needs, 2.2 ADL needs, 2.4 Treatment needs, and 2.8 Information needs (Supplementary Table 3).

Results of the Cox proportional hazards regression analysis used the NAT:PD-HF sum score of needs over items 2.1 to 2.8 as a predictor. To help with distribution of the score, the NAT:PD-HF sum score was dichotomized into 0-1 significant needs, and 2+ significant needs, with 0-1 significant needs as the reference category. The unadjusted median time to death was almost 3.4 times less for those with 2+ significant needs in the NAT:PD-HF (*Md* = 194 days [95% CI: 44-237 days]) than for those with 0 to 1 needs (*Md* = 502 days [95% CI: 255-733 days]) (see Figure 1a). The log rank (Mantel Cox) test was statistically significant with $X^2(1) = 4.1$, $p = .044$.

In the unadjusted model (Table 4), having 2+ significant needs was a significant predictor for shorter survival time (HR: 1.52, 95% CI: 1.01 – 1.74). The hazard ratio of 1.24 (95% CI: 0.85 – 1.63) for reporting 2+ significant needs in comparison to 0 - 1 needs is statistically non-significant once the MAGGIC score (HR: 1.08, 95% CI: 1.02 – 1.14) and the AKPS score (HR: 0.97, 95% CI: 0.94 – 0.99) are entered into the multivariable model as covariates (Table 4). The cumulative hazard function for the adjusted model is presented in Figure 1b.

[Please insert Table 4 about here]

[Please insert Figure 1 about here]

Discussion

These clinical data demonstrate that in the context of a specialist palliative care clinic, the NAT:PD-HF performs well regarding concurrent validity across a range of clinically important domains. Substantial agreement was demonstrated for the psychological items, patient spiritual needs, patient and carer financial/legal concerns, and information needs. The concurrent validity of the physical symptoms item was in the low moderate range.

These findings are consistent with, and add to, the original construct validation work for the NAT:PD-HF.(9,10) Waller *et al* were unable to test concurrent validity for the caregiver's concern sections, and about half of their study population were only mildly symptomatic (New York Heart Association Classes I or II), therefore few had significant functional disability. In a longitudinal cohort study of people hospitalized with heart failure, in people with at least one significant concern identified by a baseline NAT:PD-HF assessment, a higher proportion had specialist palliative care needs than not (38% vs 21%; p= 0.008).(13)

The level of agreement was comparable with the original validation of the NAT:PD-Cancer,(10) but higher than for NAT:PD-Cancer in primary care version,(25) and the version for interstitial lung disease (ILD).(26) This may reflect the communication skills of the clinicians involved (specialist palliative care clinicians in the NAT:PD-Cancer validation and in this study, in contrast to general practitioners (GPs) and respiratory clinicians in the other studies). This is not a questionnaire to be read out, but a consultation aide-memoire – therefore the level of communication and symptom/concern assessment skills of the clinician is likely to be important.

Initial NAT implementation work with respiratory clinicians indicated that additional training in symptom assessment and communication skills, particular with regard to psycho-social concerns, and the support of the palliative care team for advice and streamlined onward referral if needed, was thought necessary.(27) Similarly, a feasibility study of a Dutch translation of the NAT:PD-HF, used by heart failure nurse specialists, found that nurses lacked communication skills regarding holistic enquiry and knowledge of palliative care interventions.(28) The heart failure nurse specialists found it uncomfortable to use because they were unfamiliar with a needs-based approach to patient assessment, being used to one focusing on physiological measurement (vital signs, blood tests) and supporting pharmacological management of the heart failure. However, despite this, acceptability was rated as 7/10 on average, the nurses identified unmet needs in all patients and additional action was triggered in just under half.(28) In Campbell *et al,* all 272 NAT:PD-HF assessments were made by a member of the research team, who became proficient.(13) Other than the Dutch study, the NAT is reported to be acceptable by clinicians. Process evaluation data from a recent mixed methods feasibility study of the NAT-Cancer (primary care version) found 96% of family practitioners participants agreed or strongly agreed that they would support the NAT for clinical use.(29) Despite concerns that a holistic assessment would take a lot of time, the average time in studies shows this to be 15 to 26 minutes on average.(13,28,29) However, if the clinical culture in cardiology - or other - teams does not support holistic assessment skills, or the time to use them, then it is unlikely that the NAT:PD-HF would be implemented, embedded and become a routine for people with advanced heart failure.

The systematic nature of enquiry still renders the NAT useful even with expert holistic assessors, where, with open enquiry alone, patients on average volunteer one concern per consultation.(30) With a systematic assessment, this increases to 10 concerns – many of which are serious and distressing, but would otherwise not be volunteered.(30) Importantly, the NAT is an assessment tool used as a consultation guide and not an outcome measure, and looks at the agreement between clinician-assessed and patient-reported unmet need. Therefore, the range of strength of agreement is to be expected given i) the broad constructs examined - better agreement tends to be seen for items which are more circumscribed ("finance/legal; need for information"), ii) the distinction between broad assessment and specific outcome measurement and iii) the known discordance between clinician and patient reports.(31) The key issue is that published data to date suggest that this strength of agreement is related to changes in patient care (NAT:PD-HF),(26) and reduction in patient unmet needs (NAT:PD-C).(27,32)

There are ongoing inequalities in access to palliative care (both generalist and specialist) for people with advanced heart failure. Recognition of those needing a palliative care approach has improved; primary care studies show palliative care registration increasing from only 7% of those dying from heart failure in 2009 to 21.2% in 2014.(33) Difficulties in prognostication are reported when this approach is used in identifying who might benefit and often given as the main reason for poor palliative care access. Our data add to the growing evidence to support the use of a needs-based approach as a solution to this clinical challenge. Although we show that significant concerns on the NAT:PD-HF predicted poorer survival, it is not the tool's designed purpose, and was no longer statistically significant when performance status and the MAGGIC predictor score were added. A community based study comparing the clinical utility of the SEATTLE score and the Gold Standards Framework (GSF) palliative care indicators showed that the GSF identified nearly all patients thought to have palliative care needs, but the specificity for being in the last year of life was poor.(34) Although needs are likely to be greater in the last year of life, uncertainty regarding prognosis should not prevent patients having access to the necessary support and management for these needs either by the usual care team or, where needed, by specialist palliative care.

Strengths and limitations

This routinely collected dataset of consecutive patients attending an outpatient specialist palliative care clinic provided the opportunity to further validate the use of the NAT:PD-HF within a routine care setting after implementation. However, the level of feasibility, setting, timing, and the implementation process were not studied qualitatively or via mixed-methods designs since the evaluation of the tool's routine implementation was not the goal of the study. As described above, the fact that the NAT:PD-HF was implemented within a specialist palliative care setting, not a routine cardiology heart failure setting, may reflect that the specialist setting better supports symptom assessment and communication skills. It may also bias the results in terms of providing data on a select sample of patients that gained access to specialist palliative care,(6,8,12) therefore limiting the generalizability of the findings.

Implications for clinical practice

Our data show that a needs assessment approach – identifying the unmet needs of people with advanced heart failure, and triaging action to access appropriate clinical care (be it from the usual care team, or referring to specialist palliative care or other agencies) – will help identify those with concerns that need to be addressed now, as well as those with concerns relevant when approaching the end of their lives. Thus, routine use of needs assessments may enable improved patient experience of care quality through providing a personalized approach to planning complex heart failure care.(28,32) This is consistent with the literature showing patient benefits from clinician-administered comprehensive geriatric assessment (35) and clinician-administered cancer needs assessments.(32,36,37,38)

Predicting when the patient may die – possible at the population level, but very difficult at the individual - , only addresses the issue of care of the dying. Predicting who has significant concerns now, addresses (i) the issue of helping people with advanced disease live as well as they can for as long as they can by providing timely, good palliation alongside continuing disease-directed treatment as necessary and (ii) helps form the context within which to judge the appropriate nature of any disease-directed treatment. Although published reports do not support common concerns about the needs measure being time-consuming (the NAT:PD-C was shown not to increase the length of an oncology clinic consultation (32), and to take 15-20 minutes only on average in primary care (38)), implementation of needs assessment requires training, attention to resources, and support from the specialist palliative care team.

Implications for research

A clinical trial of effectiveness and cost-effectiveness of using the NAT:PD-HF is needed with regard to reduction in patient and carer unmet need, ideally as a hybrid design to explore concurrently issues regarding implementation. Our study identified the IPOS as a holistic tool showing overlap to the NAT:PD-HF in some of its domains. It could therefore potentially be used as an outcome measure in a clinical effectiveness trial of implementing the NAT:PD-HF into routine care. However, appropriate tools to measure the effectiveness of the identification of needs for carers of patients with advanced heart failure need to be identified through a systematic review.

In addition, the relative benefits, or optimal use of clinician-administered assessment versus patient-reported tools/measures is yet to be understood. Randomized trials of patient-reported symptoms as part of routine cancer care - when addressed by the clinical team - show benefit in both symptoms and survival.(37,39) The use of patient-reported outcomes, when these are not systematically addressed by clinicians, may worsen patient outcomes (40), possibly through raising expectations that are not realized. It is possible that use of both clinician-administered needs assessment and patient-reported outcomes would provide a “primed” clinician ready to hear patient concerns, and “primed” patients reassured of the legitimacy of bringing their concerns to the consultation.

Conclusions

The NAT:PD-HF has adequate to good concurrent validity, construct validity and moderate predictive validity to identify patients with chronic heart failure who would benefit from a palliative and supportive care approach.

Disclosure/Conflict of interest statement

All authors verify that they have no conflict of interest to disclose.

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Contributors

MJJ, FEM and JR conceived the study and design. MJJ, AK, CK, FEM and CR wrote the protocol. JR collected the data. CR and AK led on construct validity testing. CR, AK and CK conducted the analysis. All authors contributed to interpretation. MJJ, CK and CR wrote the first draft and all authors contributed to revisions and the final draft.

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Role of the funding source

The funder had no role in the study design, collection of data, analysis of data, nor interpretation of data, the writing of the report or the decision to submit the paper for publication.

Ethics approval

Hull York Medical School Ethics Committee approval was obtained (REF 20 51).

Data sharing statement

The corresponding author can be contacted regarding use of anonymized data.

Tables

Table 1. Description of key Study Measures used in this study

Measure	Details of measure	Scoring
NAT:PD-HF (9)	A clinician consultation guide of four sections totalling 20 items.	Recorded by level of concern for each item (none, some or significant), to guide the provision of appropriate support for the unmet needs of patients and their caregivers.(9)
IPOS (14)	A 17-item patient-centred questionnaire assessing palliative care related symptoms and concerns.	Each IPOS item is scored on a Likert scale from 0 - 4 (with 0 meaning no concern and 4 signifying overwhelming concern).(14) The items can be combined into three subscales: physical symptoms, emotional concerns, and concerns regarding communication/practical issues.
Zarit-6 (15)	A carer-focused questionnaire of 6 items: four items to assess personal strain and two items for role strain.(15) This is a short form of the original 22-item Zarit Burden Interview which measures carers' physical and psychosocial burden on a five-point Likert scale.	Each Zarit item is scored on a 5-point Likert-like scale from 0 to 5 (0 = never, 5 = nearly always).

AKPS (16)	Assesses the ability to perform daily living tasks relating to activity, self-care and work.	An 11-point scale in 10-point increments from 0 to 100. 100 signifies normal physical abilities with no evidence of disease. Decreasing numbers indicate reducing performance status with 10 being moribund, and 0 being deceased.
HADS (17)	A patient-rated questionnaire measuring the level of psychological distress. Seven assess the patient's anxiety levels and seven assess the patient's level of depression	All questions are rated from 0 – 3, with total scores of 0-7 being normal, 8-10 being borderline abnormal and 11-21 being abnormal.(17)
MAGGIC (18)	A prognostic score for people with heart failure composed of 13 clinical variables: age; sex; diabetes; chronic obstructive lung disease; smoking status; duration, class and medication for heart failure; ejection fraction, systolic blood pressure, serum creatinine and body mass index.	A risk calculator estimates the 1 and 3-year mortality.
Palliative Phase of Illness (19)	Used in advanced illness to describe the distinct stages of an individual's illness according to the care needs of the individual, the family and the suitability of the current care plan to address these needs.	Classification into one of five phases (unstable, stable, deteriorating, dying, deceased) with a new phase assigned whenever a clinical change requires patient and family re-assessment and modification of the existing care plan.

NAT:PD-HF: Needs Assessment Tool: Progressive Disease – Heart Failure, IPOS: Integrated Palliative Outcome Scale, Zarit-6: Zarit Caregiver Burden Interview short-form 6, AKPS: Australian-modified Karnofsky Performance Scale, HADS: Hospital Anxiety and Depression Scale, MAGGIC: Meta-analysis Global Group in Chronic Heart Failure risk score

Table 2. Demographic and clinical characteristics of included patients (*n* = 88)

	Patients	
Variable	**n**	**%; SD (range)**
Socio-demographic details		
Age: Mean	Mean: 84.9	SD: 9.6, Range: 53-100
<65 years	5	5.7
≥ 65 years	83	94
Gender		
Men	44	50.0
Women	44	50.0
Living situation		
Patient lives alone	29	33.0
Patient lives with family	48	54.5
Patient lives in nursing or residential home	11	12.5
Carer		
Patient has carer relationship	87	98.9
Patient has no carer relationship	1	1.1
Setting and clinical care		
Length of care: Mean, Median	Mean: 223.3 Median: 205	SD: 159.3 , Range: 0-487 IQR: 95.75 to 355.25
Mortality		
Patient dead (follow-up August 2020)	59	67.0
Patient alive (follow-up August 2020)	29	33.0
Length of survival (in days) Mean	Mean: 275.9	SD: 285.7, Range: 0-958
Place of death		
Home	11	12.5
Nursing home	5	5.7
Hospital	12	13.6
Hospice	11	12.5

Patient alive at follow-up	20	22.7
Missing	29	33.0
Referral source		
General Medical practitioner	66	75
Hospital Cardiology	6	6.8
Hospital Palliative care	9	10.3
Community matron	3	3.4
Internal Care Network (Community Multidisciplinary Team Meeting)	4	4.5
Preferred place of care		
Home	73	83.0
Nursing home	8	9.1
Hospice	1	1.1
Died before assessment or missing	6	6.8
Preferred place of death		
Usual place of residence	53	60.2
Nursing home	7	8.0
Hospice	13	14.8
Hospital	1	1.1
Patient undecided	6	6.8
Patient unable to express preference	2	2.3
Died before assessment or missing	6	6.8
Clinical variables		
Body Mass Index Mean	23.8	SD: 5.6, Range: 15.3-50.1
MAGGIC score Mean	31.6	SD: 5.7, Range: 21-46
Risk of dying in 1 year	77	87.5
Missing	11	12.5
Risk of dying in 3 years	77	87.5

Missing	11	12.5
Palliative Phase of illness		
Stable	33	37.5
Unstable	4	4.5
Deteriorating	44	50.0
Dying	5	5.7
Dead	2	2.3
Australia-modified Karnofsky Performance Status		
Median (range)	Median: 50	Range: 0-80
0-50	52	59.1
60-100	35	39.8
Missing	1	1.1
Cardiac conditions*		
Heart failure with reduced ejection fraction (Left ventricular dysfunction)	56	63.6
Heart failure with normal ejection fraction	18	20.4
Valvular heart disease	13	14.8
Other	1	1.1
Arrhythmic heart disease	59	67.0
Ischemic heart disease	45	51.1
Cardiomyopathy	9	10.2
Chronic kidney disease		
Stage 1 – 3b	69	78.4
Stage 4 or 5	19	21.6
Number of comorbidities Median	Median: 2	Range: 0-5
Chronic kidney disease	19	21.6
Cardiovascular Accident (Stroke)	14	15.9
Dementia	12	13.6

Depression	11	12.5
Parkinson’s Disease	1	1.1
Endocrine Disease	39	44.3
Respiratory Disease (e.g. Chronic obstructive pulmonary disease)	31	35.2
Cancer	19	21.6

*Patients could have more than one cardiac condition.

SD: standard deviation, MAGGIC: Meta-analysis Global Group in Chronic Heart Failure risk score

Table 3. Cohen's Kappa, PABAK and percentage agreed of the severity of the concerns between NAT:PD-HF and IPOS items.

			Severity of concern			
Domain	**NAT:PD-HF item**	**Comparison measure**	**n**	**Cohen's k (95% CI)**	**PABAK (95% CI)**	**% Agreed**
Physical symptoms	2.1 Patient physical symptoms	IPOS physical subscale	80	0.19 (p = 0.016)	0.33 (0.11 - 0.54)	0.66
	3.1 Caregiver distress about physical symptoms	IPOS Q4 Family anxiety	66	0.39 (p = 0.001)	0.42 (0.2 - 0.65)	0.71
	2.2 Patient ADL problems	AKPS score	86	0.46 (p < 0.001)	0.51 (0.33 - 0.7)	0.76
	3.2 Caregiver difficulty providing care	Zarit-6 sum score		0.05 (p = 0.386)	0.13 (-0.14 - 0.4)	0.56
Psychological	2.3 Patient psychological symptoms	IPOS Q3 Patient anxiety	71	0.16 (p = 0.088)	0.49 (0.29 - 0.7)	0.75
		IPOS Q5 Depression	71	0.26 (p = 0.019)	0.63 (0.45 - 0.82)	0.82
		IPOS Q7 Sharing feelings	72	0.01 (p = 0.987)	0.39 (0.17 - 0.61)	0.69
		HADS depression score	53	0.06 (p = 0.611)	0.43 (0.19 - 0.68)	0.72
		HADS anxiety score	53	0.03 (p = 0.818)	0.66 (0.45 - 0.87)	0.83
	4.2 Caregiver grief impending death	No comparator	-	-	-	-
Practical	2.4 Patient concerns treatment	IPOS Q3 Patient anxiety	71	0.11 (p = 0.290)	0.44 (0.22 - 0.65)	0.72
	3.4 Caregiver concerns treatment	No comparator	-	-		-
Spiritual	2.5 Patient spiritual concerns	IPOS Q6. Feeling at peace	70	0.23 (p = 0.017)	0.6 (0.41 - 0.79)	0.80

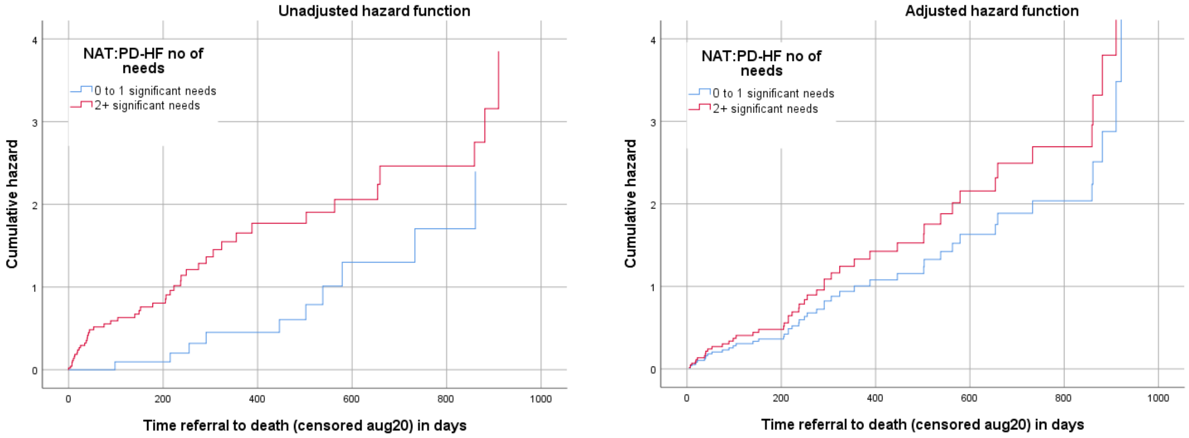
Psychosocial	2.6 Patient financial/legal concerns	IPOS Q9. Practical problems	73	0.25 (p = 0.021)	0.75 (0.6 - 0.91)	0.88
	2.7 Patient cultural factors	No comparator	-	-		-
	3.5 Caregiver financial/legal concerns	IPOS Q9 Practical problems	68	0.22 (p = 0.040)	0.82 (0.69 - 0.96)	0.91
Carer strain	3.3 Caregiver difficulty coping	IPOS Q4 Family anxiety	66	0.25 (p = 0.013)	0.33 (0.1 - 0.57)	0.67
		Zarit-6 sum score	55	0.05 (p = 0.147)	0.2 (-0.06 - 0.46)	0.60
	3.6 Family problems relationships	IPOS Q4 Family anxiety	66	0.03 (p = 0.236)	0.3 (0.07 - 0.54)	0.65
		Zarit-6 sum score	55	0.03 (p = 0.124)	0.16 (-0.1 - 0.43)	0.58
	4.1 Caregiver multidimensional problems	IPOS Q4 Family anxiety	66	0.01 (p = 0.730)	0.21 (-0.03 - 0.45)	0.61
		Zarit-6 sum score	54	0.05 (p = 0.015)	0.22 (-0.04 - 0.49)	0.61
Information needs	2.8 Patient information needs	IPOS Q8. Information needs	72	0.24 (p = 0.040	0.53 (0.33 - 0.73)	0.76
	3.7 Caregiver information needs	IPOS Q8 Information needs	62	0.25 (p = 0.040)	0.68 (0.49 - 0.86)	0.84

PABAK – Prevalence-Adjusted Bias-Adjusted Kappa, n: sample size, CI: confidence interval, k: kappa

Table 4. (a) Univariable analysis, (b) Multivariable analysis; (*) HR based on Cox proportional hazard models; (**) adjusted for MAGGIC score, and AKPS score.

<table>
<tr><th colspan="4">(a) Univariable analysis (N = 88 / events 58) – Likelihood ratio test = 4.0 for 1 df, p = 0.044</th></tr>
<tr><td>NAT:PD-HF Patient needs categorised</td><td>HR for time-to-death*</td><td>95% CI</td><td>p-value</td></tr>
<tr><td>0 to 1 (reference)</td><td>1.00</td><td>-</td><td>-</td></tr>
<tr><td>2 +</td><td>1.52</td><td>1.01 – 1.74</td><td>0.048</td></tr>
<tr><th colspan="4">(b) Multivariable analysis** (N = 88 / events 49) – Likelihood ratio test = 16.0 for 3 df, p = 0.001</th></tr>
<tr><td>NAT:PD-HF Patient needs categorised</td><td></td><td></td><td></td></tr>
<tr><td>0 to 1 (reference)</td><td>1.00</td><td>-</td><td>-</td></tr>
<tr><td>2 +</td><td>1.24</td><td>0.85 – 1.63</td><td>0.449</td></tr>
<tr><td>MAGGIC score</td><td>1.08</td><td>1.02 – 1.14</td><td>0.007</td></tr>
<tr><td>AKPS</td><td>0.97</td><td>0.94 – 0.99</td><td>0.046</td></tr>
<tr><td colspan="4">HR: Hazard ratio, CI: Confidence Interval, MAGGIC: Meta-analysis Group</td></tr>
</table>

Figures



a) b)

Figure 1. Hazard function for NAT:PD-HF needs categories – (a) unadjusted and (b) adjusted for MAGGIC score and AKPS score [analysis based on the imputed dataset]

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