Clinical Research in Cardiology
https://doi.org/10.1007/s00392-021-01912-0

ORIGINAL PAPER

Feasibility and effectiveness of a multidimensional post-discharge disease management programme for heart failure patients in clinical practice: the HerzMobil Tirol programme

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Received: 10 May 2021 / Accepted: 13 July 2021

Abstract

Aims It remains unclear whether transitional care management outside of a clinical trial setting provides benefits for patients with acute heart failure (AHF) after hospitalization. We evaluated the feasibility and effectiveness of a multidimensional post-discharge disease management programme using a telemedical monitoring system incorporated in a comprehensive network of heart failure nurses, resident physicians, and secondary and tertiary referral centres (HerzMobil Tirol, HMT),

Methods and results The non-randomized study included 508 AHF patients that were managed in HMT ($n=251$) or contemporaneously in usual care (UC, $n=257$) after discharge from hospital from 2016 to 2019. Groups were retrospectively matched for age and sex. The primary endpoint was time to HF readmission and all-cause mortality within 6 months. Multivariable Cox proportional hazard models were used to assess the effectiveness. The primary endpoint occurred in 48 patients (19.1%) in HMT and 89 (34.6%) in UC. Compared with UC, management by HMT was associated with a 46%-reduction in the primary endpoint (adjusted HR 0.54; 95% CI 0.37–0.77; $P<0.001$). Subgroup analyses revealed consistent effectiveness. The composite of recurrent HF hospitalization and death within 6 months per 100 patient-years was 64.2 in HMT and 108.2 in UC (adjusted HR 0.41; 95% CI 0.29–0.55; $P<0.001$ with death considered as a competing risk). After 1 year, 25 (10%) patients died in HMT compared with 66 (25.7%) in UC (HR 0.38; 95% CI 0.23–0.61, $P<0.001$).

Conclusions A multidimensional post-discharge disease management programme, comprising a telemedical monitoring system incorporated in a comprehensive network of specialized heart failure nurses and resident physicians, is feasible and effective in clinical practice.

Keywords Heart failure · Disease Management programme · Telemedicine · Transitional care

Introduction

Heart failure (HF) is a global health problem with increasing incidence and prevalence [1]. Hospitalization for acute HF, which either marks the onset of the disease or—more often—abruptly interrupts the course of the disease, is associated with higher mortality and recurrent hospitalization [2, 3]. In an European survey, 1-year mortality was 23.6% for individuals hospitalized with acute HF, compared with 6.4% for outpatients with chronic HF [2]. The majority of readmissions occurs early after hospital discharge: about a quarter of patients are readmitted within the first month [4] with a 50% proportion of HF-related causes of readmission [5]. The time window associated with a particularly high risk, however, extends beyond the first 30 days with the same percentage of patients being readmitted in the time from

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Published online: 16 July 2021

day 31–180 as from day 0–30 [6]. The risk of death appears to increase with each subsequent readmission for HF [7]. Frequent readmissions during this vulnerable period are mostly due to the progressive nature of HF, poor self-management, and recurrent signs and symptoms resulting from volume overload [8]. This vicious cycle negatively affects the patients' quality of life (QoL) [9], and mortality [3] and increase the overall healthcare costs [10].

Systematic reviews suggest that interventions to improve the care transition process can improve clinical outcome compared with routine care [11–13]. Consequently, care programmes designed to facilitate transitions from hospital to home are strongly recommended [14–16].

Nevertheless, there are still a number of open questions. Recent literature indicates conflicting results with regard to the appropriateness of reducing the 30-day readmission rate: while there is evidence that despite a US-wide reduction in 30-day readmissions, 30-day and 1-year mortality simultaneously increased [17], this was clearly contested by another study [18]. Also, many transitional programmes were tested in single centres with limited numbers of patients, using various modes of intervention such as nurse home visits, disease management clinics, follow-up calls or telemonitoring. Moreover, the transfer of research-derived approaches of transitional care into daily clinical practice may be difficult because many of them require intensive in-person interactions that are not always acceptable to patients [19] and because reimbursement by the respective health system cannot always be guaranteed [20]. As a result, there are only a few implementations of large-scale transitional care programmes outside of clinical trials, and sustainable reimbursement strategies have not been achieved [21].

HerzMobil Tirol (HMT) is a multidimensional post-discharge disease management programme for heart failure patients using a telemedical monitoring system incorporated in a comprehensive network of specialized heart failure nurses, resident physicians, and secondary and tertiary referral centres [22]. Starting in 2012, the programme went through several project phases until it was finally adopted into regular service in 2017 [23]. This also ensured reimbursement of the programme by the social security system. From 2016, the programme was gradually extended to cover the entire region of Tyrol in the west of Austria. In 2018, it was adopted into the region of Styria in the south of Austria [24].

Our aim was to assess the feasibility and effectiveness of a non-trial, post-discharge disease management programme such as HMT to reduce HF readmission and all-cause mortality. Moreover, the effects of the programme on disease severity and patients' self-care behavior were studied.

Methods

Setting

A multidisciplinary team developed the intervention based on established elements and shaped to patient needs (Table 1). The programme builds on several pillars: (i) patient education to improve patient empowerment; (ii)

Table 1 Characteristics of HerzMobil Tirol (HMT)

Components of HMT	Delivery personnel	Intervention content
Hospital	In-hospital specialist HF cardiologist/internist	Inclusion of patients in the programme Design individualized treatment plans that are immediately transferred to all stakeholders
Nurse case management	Specialty-trained HF nurse	Standard-of-care HF education programme Home visits Telephone support
Telemonitoring (supervision is facilitated by an automatic event detection program that signals the need for therapeutic decisions)	Specialty-trained HF nurse Resident network physician	Daily disease monitoring via supervision of remotely transmitted patient-associated data Forwarding of information about worsening of disease or warnings from TM that cannot be processed independently to the network physician Weekly disease monitoring via supervision of remotely transmitted patient-associated data
Network of primary care providers	Resident network physician	Assessment of patients within first week after discharge from hospital Two more regular office visits at weeks 4 and 12 Monitoring of laboratory parameters Optimization of evidence-based HF medication Reacts in a timely manner in case of disease deterioration
Programme coordination	Coordinator	Orchestrates all stakeholders and manages efficient cooperation of partners involved

nurse-led care for early detection of imminent decompensation; (iii) patient-held mobile phone for daily data acquisition and transmission of blood pressure, heart rate, body weight, well-being, and drug intake, including nurse- and physician-controlled telemonitoring of these data; (iv) continuous optimization of guideline-based HF therapy for long-term stabilization; and finally, (v) network communication to assure comprehensive HF management across venues.

Telemedical technology at HerzMobil Tirol

HerzMobil Tirol uses an integrated technical concept called Keep-In-Touch (KIT) to facilitate efficient and reliable daily data documentation and transfer [25]. Every patient is provided a blood pressure and heart rate monitor and a weighing scale as well as a specially configured smartphone for daily data acquisition and transmission. Patients can call a helpdesk in case of technical problems. As most of the patients are elderly patients, the dialogue-oriented and process-supporting KIT technology and the mobile app are designed to support the patients at home in easy and secure handling of the daily data acquisition process [22]. To identify upcoming adverse events, signal processing algorithms are used to analyse the transmitted physiological data [22]. Automatic event detection indicates the need for immediate actions and fosters attention to those patients who might need early therapeutic intervention. The limits used for automatic event detection are individually defined and regularly adapted for each patient by the network physician. The web-based telehealth software is made available to all stakeholders (network physicians, nurses, helpdesk, and network coordinator) and supports their individual tasks through user-specific dashboards.

Patients

Patients ≥ 18 year were eligible when hospitalized with signs and symptoms of decompensated heart failure requiring IV diuretics, irrespective of the underlying left ventricular ejection fraction (LVEF). Exclusion criteria included multimorbidity (Charlson Comorbidity Index > 6), dementia, and lack of willingness to participate. Inclusion criteria for the retrospectively defined control group were hospitalization for decompensated heart failure requiring IV diuretics irrespective of the underlying LVEF, and no prior participation in the HMT programme. Only patients who were admitted to hospital contemporaneously as the study patients between 2016 and 2019 were taken into account.

Recruitment and assignment

Patients for the HMT cohort were reported to the programme coordinator from four secondary (internal medicine) and one tertiary (cardiology) referral centres in Tyrol at the discretion of the respective internist or cardiologist. Patient selection was influenced by the coincidence of admission to wards participating in the programme and by the capacity of the care programme at any given time. This triggered visits from a specialized HF nurse from the HMT network, who invited the patient to participate and—upon consent—started with patient education. Patients for the control group (UC—usual care) were recruited retrospectively from the database of Tirol Kliniken GmbH, the largest healthcare provider in Tyrol. Tirol Kliniken GmbH operates four secondary and one tertiary care centre with a total of eight departments of internal medicine (Fig. 1).

Post-discharge care

HMT (Table 1)

Detailed information on the integrated care process and the role of the members of the multidisciplinary HMT team have been published previously [23]. In short: patients enter the HMT programme during hospitalization for acute heart failure (AHF). Patient education is delivered by specialized heart failure nurses. On discharge, each patient is assigned to a resident network physician near his or her home. Network physicians supervise the management of the patient and gradually optimize evidence-based therapy. Discharge information including a detailed treatment plan from the hospital is communicated to the HMT network. Within HMT, patients are supervised for 3 months. Telemedicine patient data on current health, weight, heart rate, blood pressure and medication use are reviewed daily by HF nurses and weekly by network physicians. Out-of-limit data are automatically signaled and reviewed daily so that interventions, for example, adjustment of diuretics, can be implemented immediately. Face-to-face visits of the patient with the network physician are scheduled 1, 4, and 12 weeks after discharge.

HF nurses monitor patients' compliance with medication, maintain telephone contact with patients if necessary and adjust HF medication according to the network physicians' instructions. Additionally, a home visit by the HF nurse is scheduled immediately after discharge to complete disease- and equipment-related education and to ensure that prescribed medication is available.

At the end of the managed care programme, structured transfer of patients to regular care is organized. Regular heart failure network meetings of physicians and nurses are scheduled every 3 months.

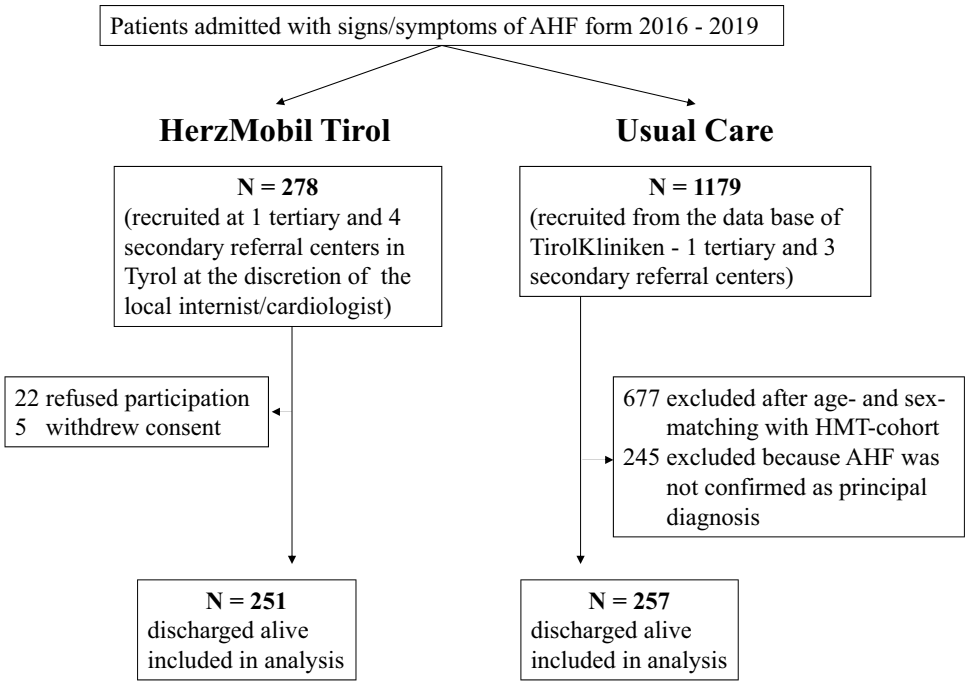

Fig. 1 Flow chart of the study population

Usual care

Patients in UC underwent standard post-discharge planning, which typically included treatment plans and comprehensive discharge letters. In most cases, the actual follow-up of the patients was unstructured and left to the respective family doctor or internist.

Data collection and follow-up

Patients underwent standardized evaluation including medical history, 12-lead ECG, and echocardiography. Physical status, blood chemistry and medication, and—in a subgroup of patients—questionnaires on patients' self-empowerment were obtained before discharge. Number, duration, and causes of readmissions were taken from discharge letters. Information on death was retrieved from patients' charts, family doctors and relatives, and official documents of death.

Informed consent was obtained from patients in the HMT programme. The study complied with the Declaration of Helsinki and Good Clinical Practice (GCP) principles and was approved by the Ethics Committee of the Medical University of Innsbruck (AN2015-0131, session number 350/4.2).

Outcome measures

Effectiveness assessment was based on the primary endpoint, which was defined as the composite of death from any cause and readmission for AHF at 6 months. Secondary endpoints included the components of the primary endpoint as well as 1- and 3-month readmission for AHF and 1-year all-cause mortality. Patient empowerment was assessed by the using of the European Heart Failure Self-care Behaviour Questionnaire (EHFScB-9) [26] at baseline and after 3, 6, and 12 months.

Statistical analysis

Given the observational nature of the data, management allocation was not randomly assigned in the study population. Therefore, we performed age- and sex-matching to define a control group for usual care. For this purpose, we used 1179 patients from the Tirol Kliniken GmbH database who were categorized with an ICD-10 code for AHF. After adjustment for patients for whom AHF could not be confirmed as the primary diagnosis at admission or who did not live in the catchment area of the Tirol Kliniken GmbH and therefore could not be tracked exactly, 257 patients remained for analysis. Patients in both groups discharged alive from hospital were included in the analysis (Fig. 1).

The combined endpoint, HF readmission and mortality were plotted with a Kaplan–Meier curve. Cox proportional regression models (univariate and covariate-adjusted) were used to estimate the association between HMT and usual care management and outcome measures. Hazard ratios, 95% CIs and *P* values were calculated. Time alive and out of hospital was estimated from extended Kaplan–Meier analyses.

We assessed the robustness of our main results using a multivariate Cox regression model that included age, sex, predominant cause of HF, LV-EF, and NT-proBNP that

were based on clinical relevance and data from the existing literature. In addition, diabetes mellitus as the only baseline variable, which was different between HMT and UC and significantly associated with the primary endpoint was included in the model. Dichotomization of variables was either performed at clinically relevant cu-toff values (LV-EF < 40% or > 40%, eGFR < 60 ml/min/1.73m^2 or > 60 ml/min/1.73m^2) or the cut-off value was defined at the median of the variable (age, MAGGIC score, CCI) or was naturally predefined (sex, ICU stay, atrial fibrillation, GDMT).

To compare repeated hospitalizations during 6-month follow-up between groups, we used the Andersen-Gill model, which examines times between events and is a generalization of the Cox proportional hazards model [27]. In addition, the cumulative incidence of hospitalization was calculated for each treatment group. To mitigate the effect of survivor bias, we used the Ghosh and Lin method to estimate the cumulative incidence of hospitalization by treating death as a competing risk [28].

Continuous data were tested for normal distribution using the Kolmogorov–Smirnov test. Categorical variables are presented as percentage (%), continuous variables as mean (standard deviation (SD)) or median (25th and 75th percentile). Between-group comparisons were performed with the *t*-test, Mann–Whitney *U* test or Pearson's chi-squared test, as appropriate.

A two-sided *P* value of 0.05 was considered to be statistically significant. All calculations were performed using the SPSS statistical package, version 26.0 (SPSS Inc., Chicago, IL, USA).

Results

Between 1 April 2016, and 31 October 2019, 278 patients were screened for inclusion into HerzMobil Tirol. Of these, 22 patients refused to participate in the programme (never beginner) and 5 patients dropped out early during the programme. Accordingly, 251 patients were included in analysis. Patients for the usual care group (UC), which eventually included 257 patients, were retrospectively screened during the same period. A flow chart of the study population is shown in Fig. 1.

Patient baseline characteristics

Baseline characteristics of the entire study population are summarized in Table 2. Despite the non-randomised design, patients in the HMT and UC groups were well matched for the majority of clinical and demographic variables. Some differences, however, have to be noted: A significant higher percentage in HMT had atrial fibrillation (52.2% vs 40.5%) and lower LV-EF (36.8 ± 13.8 vs 42.1 ± 14.5) and lower systolic blood pressure (120.6 ± 19.0 vs 126.8 ± 21.7) compared to UC. Conversely, the percentage of patients in UC was higher for current smoking (26.8% vs 13.9%) and diabetes mellitus (41.6% vs 28.4%). The median length of hospital stay and the percentage of patients with intensive care unit admissions during the index hospitalization were comparable in both groups (9.0 (6–14) days and 15.1% in HMT vs. 9 (5–17) days and 16.3% in UC, respectively). The percentage of patients with guideline-directed medical therapy (GDMT = combination of ACEi, ARB or ARNI plus beta blocker plus aldosterone antagonist) at discharge in patients with HFrEF was significantly higher in HMT (55.0% vs 39.4%) whereas diuretics were equally distributed.

Primary endpoint

Follow-up data on HF readmission after 6 months and 1-year mortality was available in all patients.

The composite of hospitalization for worsening heart failure or all-cause mortality within 6 months occurred in 48 patients (19.1%) in HMT and 89 (34.6%) in UC. The cumulative incidence curves for the primary effectiveness endpoint are shown in Fig. 2a. The composite endpoint was significantly lower with HMT than with UC in the multivariate Cox regression analysis (HR 0.54; 95% CI 0.37–0.77, $P = 0.001$) (Table 3).

The results of the subgroup analyses of the primary outcome in post hoc selected clinically relevant subgroups showed consistent effectiveness across the subgroups stratified by sex, age (< 73 years or ≥ 73 years), left ventricular ejection fraction (< 40% or ≥ 40%), renal function (estimated GFR, < 60 ml/min/1.73 m^2 or ≥ 60 ml/min/1.73 m^2), Charlson Comorbidity Index (< 3 or ≥ 3), MAGGIC score (< 27 or ≥ 27), ICU admission, atrial fibrillation, and GDMT (yes or no) in a subgroup of patients with HFrEF (Fig. 3). No interactions were found for these variables with the effectiveness of HMT (Table S1). The robustness of the effect of HMT on the primary end point was further confirmed when baseline characteristics that differed significantly between groups (BMI, systolic blood pressure, LV-EF, current smoking, and GDMT at discharge) were found not to be associated with the primary endpoint (Table S2). Diabetes mellitus as the only exception was included in the multivariate Cox regression model (Table 3).

The composite of recurrent HF hospitalization and death within 6 months was found in 124 patients in UC and 78 in HMT; the respective rates per 100 patient-years were 108.2 in UC and 64.2 in HMT.

To assess the impact of death on hospitalization rates, estimates of the cumulative number of heart failure hospitalizations were calculated using a method that allows for mortality as a competing risk [28]. The estimated rate ratio for recurrent HF hospitalizations in the HMT group, as

Table 2 Patient baseline and treatment characteristics

Variable	HerzMobil ($n=251$)	Usual care ($n=257$)	P value
Age, years	69.5 ± 11.9	71.1 ± 10.8	0.151
Female, *n* (%)	75 (29.9%)	83 (32.3%)	0.557
Body mass index, kg/m^2	28.3 ± 5.8	27.3 ± 5.6	0.029
HF first diagnosed > 18 months ago, *n* (%)	102 (40.6%)	113 (44.0%)	0.447
Index hospitalization for HF			
De-novo HF	100 (39.8%)	90 (35.0%)	0.262
Length of stay, days	9 (6–14)	9 (5–17)	0.370
ICU admission, *n* (%)	38 (15.1%)	42 (16.3%)	0.710
Predominant cause of HF, n (%)			
Ischemic heart disease	71 (28.3%)	84 (32.7%)	0.282
Hypertensive heart disease	21 (8.4%)	25 (9.7%)	0.593
Dilated cardiomyopathy	89 (35.5%)	77 (30.0%)	0.187
Valvular heart disease	25 (10.0%)	19 (7.4%)	0.304
Others	45 (17.9%)	52 (20.2%)	0.509
NYHA functional class, *n* (%)			0.180
II	66 (26.3%)	83 (32.3%)	
III	182 (72.5%)	168 (65.4%)	
IV	3 (1.2%)	6 (2.3%)	
Measurements			
Systolic blood pressure, mmHg	120.6 ± 19	126.8 ± 21.7	0.001
Heart rate, /min	74.9 ± 13.3	77.9 ± 17.5	0.197
LVEF (%)	36.8 ± 13.8	42.1 ± 14.5	< 0.001
HFrEF (< 40%)	149 (59.6%)	109 (42.4%)	
HFmrEF (40–50%)	47 (18.8%)	56 (21.8%)	
HFpEF (> 50%)	54 (21.6%)	92 (35.8%)	
Medical history, *n* (%)			
Current smoker	35 (13.9%)	69 (26.8%)	< 0.001
Myocardial infarction	62 (24.8%)	75 (29.2%)	0.267
CRT and/or ICD	51 (20.3%)	43 (16.7%)	0.298
Comorbidities, *n* (%)			
Atrial fibrillation	131 (52.2%)	104 (40.5%)	0.027
Left bundle brunch block	63 (25.2%)	60 (23.3%)	0.626
Hypertension	179 (71.6%)	195 (75.9%)	0.274
Diabetes mellitus	71 (28.4%)	107 (41.6%)	0.002
COPD	62 (24.8%)	62 (24.5%)	0.940
Neoplasia	39 (15.6%)	41 (16.0%)	0.913
pAVK	36 (14.4%)	50 (19.5%)	0.129
Stroke	25 (10.0%)	23 (8.9%)	0.686
Charlson Comorbidity Index	2.8 ± 1.5	2.8 ± 1.6	0.996
MAGGIC risk score	26.8 ± 5.5	27.8 ± 5.8	0.061
Laboratory parameters			
Creatinine (mg/dl)	1.25 (1.0–1.6)	1.25 (1.0–1.7)	0.995
eGFR (ml/min/1.73m2)	42.55 (32.9–55.4)	42.6 (30.0–60.5)	0.822
Sodium (mmol/l)	140 (138–142)	140 (138–142)	0.584
NT-proBNP (ng/l)	2991 (1750–5459)	3486 (1459–7204)	0.367
Heart failure medication			
All patients			
ACEi, ARB or ARNI, *n* (%)	249 (99.2)	168 (65.4)	< 0.001
Beta-Blocker, *n* (%)	202 (80.5)	193 (75.1)	0.145
Aldosterone antagonist, *n* (%)	147 (58.6)	98 (37.8)	< 0.001
Diuretic, *n* (%)	224 (89.2)	213 (82.9)	0.041

Table 2 (continued)

Variable	HerzMobil ($n=251$)	Usual care ($n=257$)	P value
HFrEF			
ACEi, ARB or ARNI, *n* (%)	132 (88.6)	80 (73.4)	0.003
Beta blocker, *n* (%)	125 (83.9)	92 (84.4)	1.00
Aldosterone antagonist, *n* (%)	102 (68.5)	58 (53.2)	0.014
Diuretic, *n* (%)	132 (88.6)	94 (86.2)	0.573
GDMT, *n* (%)	82 (55)	43 (39.4)	0.017

Data from 508 patients are reported as mean (±standard deviation), median (25th–75th percentile), or number (percentage)

HF heart failure, *ICU* intensive care unit, *NYHA* New York Heart Association, *LVEF* left ventricular ejection fraction, *HFrEF* heart failure with reduced ejection fraction, *HFmrEF* heart failure with mid-range ejection fraction, *HFpEF* heart failure with preserved ejection fraction; coronary artery disease, *NT-proBNP* N-terminal pro-B-type natriuretic peptide, *CRT* cardiac resynchronization therapy, *ICD* implantable cardioverter-defibrillator, *COPD* chronic obstructive pulmonary disease, *eGFR* estimated glomerular filtration rate, *ACEi* angiotensin-converting-enzyme inhibitor, *ARB* angiotensin-receptor blocker, *ARNI* angiotensin-receptor-neprilysin inhibitor, *GDMT* guideline-directed medical therapy (=treatment with all three substance classes)

compared with the UC group, was 0.41 (95% CI 0.29–0.55, $P<0.001$) (Table 3).

Time alive and out of hospital within 6 months was 158.3 ± 47.5 days in UC and 172.8 ± 23.7 in HMT. A calculated overall decrease of days lost to heart failure hospitalizations and death (− 14.59 ± 3.35 days per patient; $P<0.001$) was observed in the HMT arm.

Secondary endpoints

Heart failure hospitalization

Of the 508 patients analysed, 112 (22.0%) had at least 1 admission for worsening HF within 6 months. In total, 155 hospital admissions due to HF were registered in this period.

There were 44 (17.5%) patients with at least one HF-hospitalization in HMT after 6 months, compared with 68 (26.5%) in UC. This represents a 32% relative, although non-significant risk reduction (HR 0.68; 95% CI 0.45–1.02%, $P=0.061$) in the multivariate Cox regression model (Table 3). Figure 2b shows the unadjusted cumulative incidence curves.

One- and 3-month HF-hospitalization were 18 (7.2%) and 35 (13.9%) in HMT and 27 (10.5%) and 61 (23.7%) in UC. In-between group comparison using the log-rank test was not significant for 1 month ($P=0.185$) but was significant for 3-month readmission ($P=0.006$).

The number of recurrent heart failure hospitalizations in individual patients ranged from 1 to 5. Overall, 5.9% of patients experienced two or more hospitalizations within 6 months. By 6 months, the cumulative number of heart failure hospitalizations per 100 patients was 27.5 in HMT compared with 33.5 in UC, a treatment difference of 6.0 per 100 patients.

The crude rate of heart failure hospitalizations per 100 patient-years of follow-up was calculated by dividing the total numbers of heart failure hospitalizations by the total follow-up duration of all patients in each group. In the HMT and UC groups, there were a total of 69 and 86 HF hospitalizations over 121.5 years and 114.6 years of follow-up, respectively. Thus, heart failure hospitalization rates per 100 person-years were 56.78 in HMT and 75.04 in UC, a rate ratio of 0.41 (95% CI 0.29–0.55, $P<0.001$) (Table 3).

The bar plot distribution of recurrent heart failure hospitalization per month and per patients at risk is shown in Figure S1a.

All-cause mortality

Of 508 patients analysed, 91 (17.9%) died after 1 year. Overall, 25 patients (10.0%) died in HMT, compared with 66 (25.7%) in UC (Figure S1b). Multivariate Cox regression analysis showed a 62% risk reduction (HR 0.38; 95% CI 0.23–0.61, $P<0.001$) for individuals with HMT compared with UC (Table 3). Figure 2c shows the unadjusted cumulative incidence curves. Death events within 1, 3, and 6 months occurred in 1 (0.4%), 4 (1.6%), and 9 (3.6%) patients in HMT and 10 (3.9%), 28 (10.9%), and 38 (14.8%) in UC, respectively (Figure S1b). Adjusted log-rank comparison between groups was significant at each period ($P<0.05$) (Tables 3 and S3).

Heart failure severity

In the HMT group, clinical evaluation at 3 months, which was available in 233 patients, demonstrated a significant reduction in NYHA functional class (1.9 ± 0.71) compared to baseline (2.8 ± 0.46) ($P<0.001$). Improvement of at least 1 NYHA functional class was noted in 158 patients (67.8%)

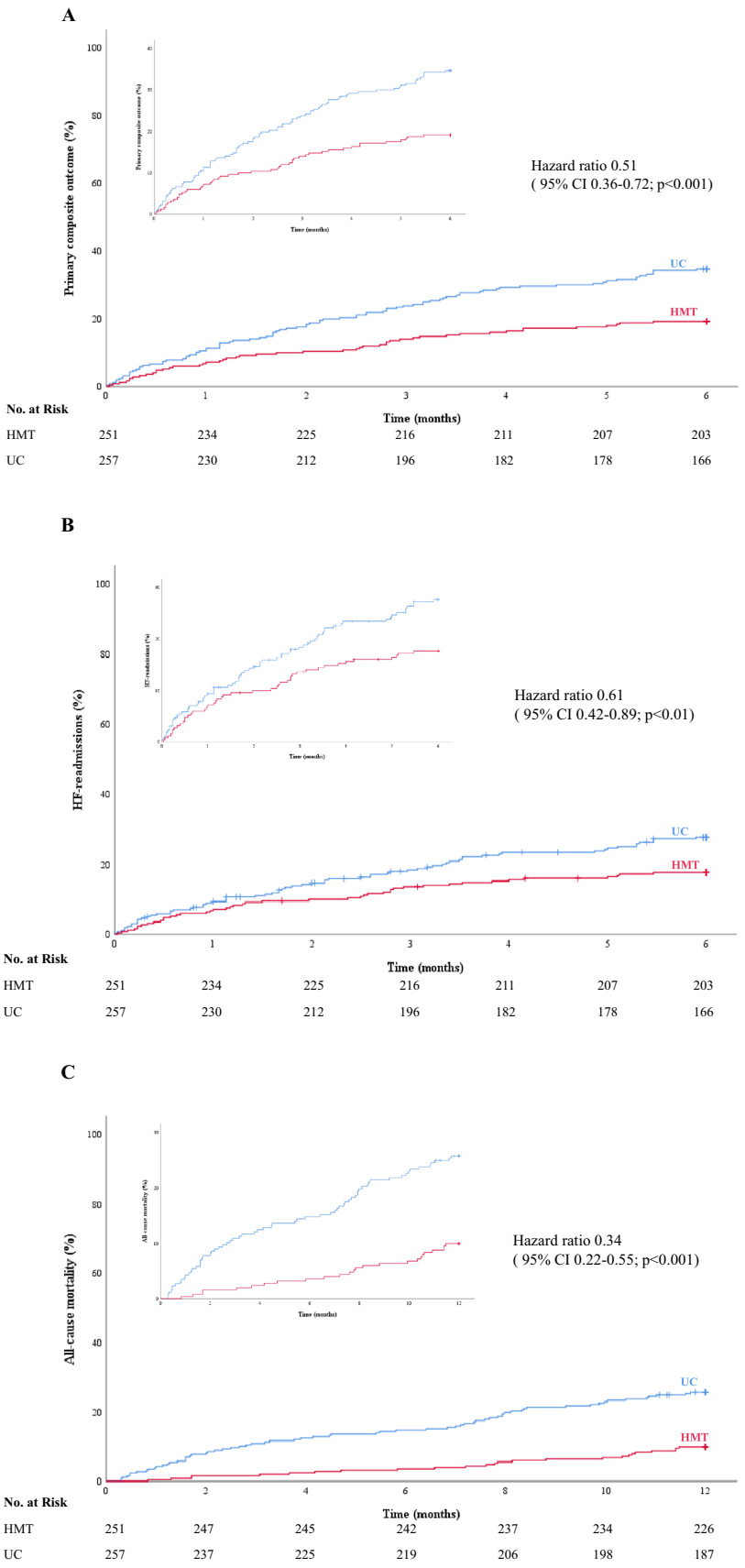

Fig. 2 The primary outcome was a composite of heart failure readmission or all-cause mortality, whichever occurred first. The cumulative incidence of the primary composite outcome (Panel A), heart failure readmissions (Panel B) and all-cause mortality (Panel C) was estimated using the Kaplan–Meier method. Hazard ratios and 95% confidence intervals were estimated using univariate (shown here) and multivariate Cox regression models with the HMT group as an explanatory variable. Each inset shows the same data on an expanded y axis. *HMT* HerzMobil Tirol, *UC* usual care, *CI* confidence interval

Table 3 Outcome analysis

Variable	HMT $n=251$	Usual care $n=257$	Unadjusted hazard ratio (95% CI)	*P* value	Adjusted hazard ratio (95% CI)	Adjusted *P* value
Composite of 6-month HF hospitalization and all-cause mortality, *n* (%)	48 (19.1)	89 (34.6)	0.51 (0.36–0.72)	< 0.001	0.55 (0.38–0.80)	0.002
Six-month all-cause mortality, *n* (%)	9 (3.6)	38 (14.8)	0.23 (0.11–0.37)	< 0.001	0.23 (0.11–0.49)	< 0.001
Six-month HF hospitalization, *n* (%)	44 (17.5)	68 (26.5)	0.61 (0.42–0.89)	0.01	0.68 (0.45–1.02)	0.061
Six-month recurrent HF hospitalization, *n* (% per 100 patient-years)[a]	69 (56.8)	86 (75.04)	0.57 (0.39–0.83)	< 0.001		
Six-month recurrent HF hospitalization adjusted for mortality (death events)[b]	9	38	0.41 (0.29–0.55)	< 0.001		
One-year all-cause mortality, *n* (%)	25 (10.0)	66 (25.7)	0.35 (0.22–0.55)	< 0.001	0.37 (0.23–0.60)	< 0.001

Unadjusted and adjusted hazard ratios and *P* values are from logistic regressions models for the primary outcome, 6-month HF hospitalization, and 6-month and 1-year all-cause mortality. Additional models were calculated for 6-month recurrent HF hospitalization, and 6-month recurrent HF hospitalization controlled for death events. The multivariate model was controlled for age, sex, predominant cause of HF, LVEF, NT-proBNP and Diabetes mellitus

[a]The Andersen-Gill model was used to account for correlated events within a patient

[b]The Gosh and Lin method was used to estimate the cumulative incidence of HF hospitalizations by treating death as competing risk

HF heart failure, *LVEF* left ventricular ejection fraction

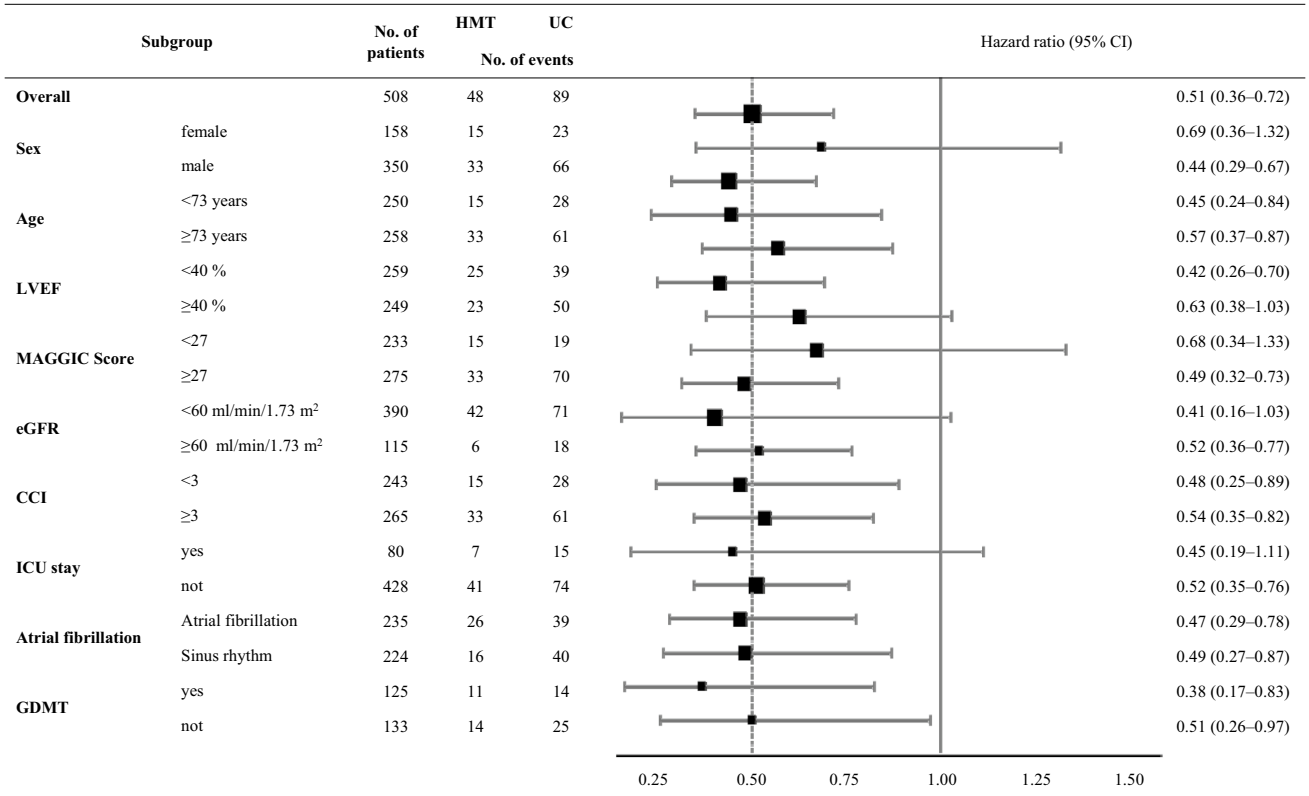

Fig. 3 Hazard ratios for the primary effectiveness endpoint events in clinical relevant subgroups. Subgroup analyses show the association between HMT and the composite outcome stratified by relevant baseline and treatment variables. Diamonds represent point estimates for the hazard ratio as compared with UC, and horizontal lines indicate the associated 95% confidence intervals. The confidence intervals have not been adjusted for multiple testing. *LV-EF* left ventricular ejection fraction, *eGFR* estimated glomerular filtration rate, *CCI* Charlson Comorbidity Index, *ICU* intensive care unit, *GDMT* guideline-directed medical therapy

whereas only 5 (2.1%) worsened and 70 (30%) remained unchanged.

Self-empowerment

Self-empowerment of patients was assessed using the EHF-ScB-9 in a subgroup of HMT patients. Completed surveys were available for 72 patients at baseline and after 3 months. 58 patients completed the survey after 6 and 12 months. EHFSB summary score improved from 22.4 (± 6.0) at baseline to 11.3 (± 2.5) ($P < 0.001$) at 3 months. Improvements remained stable in 58 patients, with scores of 12.4 (± 3.1) after 6 months and 12.3 (± 3.1), after 12 months ($P < 0.001$when compared with baseline).

Patient compliance

22 (7.9%) of 278 patients refused to participate in the HMT programme (never beginner); 5 patients (2.0%) dropped out early during the programme.

Compliance among participants remaining in the programme was high; only 6 (2.4%) of 251 patients were found to be negligent in data transfer but remained in the programme until completion after 3 months.

Discussion

The HerzMobil l Tirol (HMT) programme is a 3-month transitional care disease management programme for heart failure patients that is established in clinical routine. HMT uses a telemedical monitoring system that is integrated into a comprehensive network of healthcare providers.

In this retrospective cohort study, we found a significant reduction in the primary outcome, which was the composite of heart failure readmission and all-cause mortality after 6 months in the HMT group compared with a contemporaneously recruited control group of patients in usual care. Also, 1-year all-cause mortality was significantly reduced. The benefit on mortality was evident early after discharge and remained robust after 1 year. The reduction in HF readmissions was significant when repeated admissions per 100 patient-years of follow-up were considered and further increased when this analysis was corrected for the competing risk of death.

The results are well in line with the findings of systematic reviews showing that interventions to improve the care transition process can improve clinical outcome compared with routine care [11–13]. However, risk reduction comparable to that observed in our non-randomized retrospective analysis has not been observed in any single randomized trial to date. For instance, in a large prospective, randomized care transition intervention study (BEAT-HF) in a largely comparable patient cohort, health-coaching telephone calls combined with telemonitoring did not reduce 6-month readmission [29]. Based on the findings that heart failure readmissions in such a cohort account for about half of all hospital readmissions [5], both one- and 6-month readmission rates in this study (22.1% and 50%, respectively) were comparable to our UC cohort. The same applies to the 1- and 6-month mortality, which were 4.4% and 14.9%, respectively, in this study.

The results provided here also contradict previous findings indicating that despite a US-wide reduction in 30-day readmissions following the healthcare metric set forward by the Centres for Medicaid & Medicare Services (CMS), there was a simultaneous increase in 30-day and 1-year mortality [17, 30, 31]. The benefits in HF readmission and mortality at 30 days in the HMT group were maintained over 6 months and 1 year, respectively.

It is worth noting that mortality in the UC group was particularly high in the first months after discharge. This may indicate an inappropriate match with more advanced disease and/or more severe comorbidities or inadequate medical therapy in the UC group. However, this is not exactly reflected in the baseline characteristics. Besides age and sex, length of stay during index hospitalization, comorbidities except for diabetes, which was higher in the UC group, NT-proBNP levels, and MAGGIC score were comparable between groups. Systolic blood pressure was lower and the percentage of patients with atrial fibrillation and HFrEF was higher in the HMT group. However, although GDMT for the latter at discharge was suboptimal in both groups, which was mostly due to low blood pressure, impaired renal function, and high potassium levels, it should be noted that significantly more patients received GDMT in HMT compared with UC.

The 30-day mortality and 1-year mortality in the UC group were 3.9% and 25.7%, respectively. This was lower than the respective mortality rates in a large American cohort (6.0% and 35.8%, respectively) [32]. One-year mortality was largely as expected by the MAGGIC score (22.5 ± 10.6%) and in the recent European Heart Failure Long-Term Registry (23.6%) [2]. In addition, patients who were excluded or who refused to participate in HMT were not included in the UC group. Therefore, the UC group retrospectively identified by age- and sex- matching, although imprecise by definition, was largely comparable to the HMT group. Nevertheless, it cannot be ruled out that the effectiveness of care in HMT is overestimated. Despite this limitation, the independent association of HMT with HF readmission and mortality was supported in multivariate analyses and was consistent across multiple subgroups, including patients with HFrEF stratified by GDMT.

For affected patients, improving disease severity and days alive and out of hospital are essential to the quality of a care programme. NYHA functional class improved in the

majority (67.8%) of patients during the 3-month intervention. Importantly, the number of days survived and spent outside the hospital was significantly higher in HMT than in the UC group. In a previously published paper on a subgroup of the HMT cohort presented here, we showed that HMT intervention had a significant effect on QoL in 90-day survey respondents [23].

Feasibility

The programme was well received by eligible patients. The percentage of patients who were invited to participate yet declined was 7.9%, which was lower than expected. The reasons for this were mainly the right to domestic privacy and a lack of understanding of the seriousness of the disease. Compliance among participants was high, indicated by a low drop-out rate of 2.0%. There were no reportable problems with the implementation of the programme, either from an organizational, technical or personnel point of view. The average cost per patient in the HMT program, including personnel costs, is approximately € 2,500. In view of the sustainability of the care, a roll-out to the whole country would therefore appear to be financially viable and sensible.

Possible explanations for the beneficial results in this programme

i. Previous reviews have addressed the comparative effectiveness of transitional care services [11, 12]. It has been shown that home-visiting programmes and multidisciplinary heart failure clinics can reduce all-cause readmissions and mortality after hospitalization for HF [11, 12]. HMT is a multidimensional programme that incorporates various components of a disease management programme such as a well-connected network of multidisciplinary healthcare providers and a telemonitoring system. This systemic approach extends the possibilities of exclusive monitoring and individual response to the patients' condition by constantly reviewing the optimal drug prescription and continuously reinforcing patient education, as previously proposed [33]. The latter becomes evident in HMT, as we found an improvement in self-care behaviour as assessed by the EHF-ScB-9 after 3 months. The education effect remained robust over 12 months, i.e., 9 months after patients completed their participation in HMT. The positive effect of the program in patients with preserved ejection fraction for whom no evidence-based therapy is yet available is probably due to both the intensified monitoring and the improved self-empowerment.
ii. It is certainly important that the intervention in HMT was integrated with the physician practices caring for the patients. The effectiveness of transition of care, disease management, and telemonitoring interventions are highly dependent on how they are integrated and adhered to in practice [34]. Health telemonitoring in HMT is integrated in such a way that a collaborative HF management concept is enabled, closing the loop between patients and care providers in a timely and efficient manner and enabling continuity of care [35]. For example, the telemonitoring system used in HMT enables the processing of natural language to recognize and process medication-related notes, which in turn can be utilized to monitor and optimize medication [36, 37]. Physicians are supported by an automatic visualization of compliance with guidelines for drug prescription, which also serves the continuous optimization of drug therapy [38]. An algorithm based on artificial intelligence models is currently being developed that may even allow for more accurate prediction of HF-related events than the mere monitoring of the patients' condition, weight, heart rate, and blood pressure trends [39].
iii. Importantly, HMT at its core is based on specially trained HF nurses whose commitment and expertise is of immense importance to the success of the programme.
iv. It cannot be excluded that inadequate follow-up of UC patients in standard care contributed to the large difference in outcome between the two groups. The magnitude of the difference could also be due to biased selection of patients in the study group. These patients explicitly committed to intensified care with active participation in close monitoring and had the technical knowledge or appropriate family support to operate the KIT monitoring system.

Strength and limitations

The beneficial results shown here were not obtained under laboratory conditions of a study setting but from a routine clinical care programme. Whether this has a beneficial or detrimental effect on the results remains an open question. Nonetheless, it shows that the findings gained in earlier studies can be transferred to clinical routine. In this sense, the results obtained with HMT could be seen as a proof-of-concept. Also, the broad patient eligibility criteria increase generalizability.

Our study has several intrinsic limitations. First, this is a retrospective, non-randomized analysis. HMT was established as a routine clinical programme and prospective randomization was not envisaged by the responsible healthcare providers. A non-randomized but strictly controlled study design was therefore used, taking the advantage of a 'usual care' control group which was managed simultaneously in

the same healthcare environment as the study group. HMT and UC groups were relatively well balanced in our study, and comprehensive statistical methodologies including age- and sex-matching and multiple adjustments were applied to compensate for residual differences. Sensitivity analyses using subgroup analysis showed consistent results. The lack of significant interaction between baseline risk and clinical outcomes was robust, suggesting that the benefits of HMT over UC may relate to the procedure itself rather than patient and treatment characteristics. Nonetheless, this analysis cannot provide definitive evidence for the superiority of a transitional care programme, but rather demonstrates feasibility and effectiveness of such a programme built on multiple components in clinical practice. Secondly, readmissions for heart failure were drawn from patient records and were not assessed by a blinded committee. Thirdly, information on patient self-empowerment was only available for a subgroup of patients, which clearly limits the significance of the results on these aspects. Results are further limited by the fact that, due to the nature of this retrospective analysis, only within-group comparison of HMT was available for NYHA functional class and patient empowerment, rather than between-group comparison.

Conclusions

We evaluated a structured transitional care disease management programme for heart failure patients that is established in clinical routine. Our results show the feasibility and effectiveness of a telemedicine monitoring system in clinical practice, integrated into a comprehensive network of specialized heart failure nurses and office-based physicians, and including intensive and continuous patient education and heart failure medication optimization. These findings encourage widespread implementation of specific disease management programmes in the vulnerable phase following an acute heart failure event.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00392-021-01912-0.

Acknowledgements We thank our patients for participation in the HMT programme; the specialized HF nurses M Braunegger, T Forsthuber, I Fringer, M Hohengasser, D Kathrein, M Kreidl, V Massinger, W Neyer, M Ortner, T Ritter-Waltl, C Schlierenzauer for high-quality patient treatment; the network physicians R Eiter, R Erhart, P Faber, T Fluckinger, H Gänzer, C Gebhart, C Gelsinger, W Grander, W Gritsch, N Gruber, I Haffner, D Heininger, G. Henle, F Kirchmeyr, K Kirchmeyr, C Krismer, M Kufner, P Kufner, S Hoschek, S Huter, B Joosten-Gstrein, M Kahler, U Köllensperger, G Ladner, C Mattle-Schmid, K Moosburger, M Müller, S Nemec, M Radi, R Rieger, D Ritelli, A Süssenbacher, A Wiseman, D Wildauer, E Wöll, M Zangerle-Schmid for excellent patient care and nurse supervision; the helpdesk teams at telbiomed Medizintechnik und IT Service GmbH and of AIT Austrian Institute of Technology for technical support and constant training; the Landesinstitut für integrierte Versorgung, Tirol, and Tirol Kliniken GmbH, in particular in the person of P Lechleitner, for the provision of the infrastructure; the Federal State of Tyrol, in particular in the person of State Councillor for Health B Tilg, for continued support.

Funding HMT was funded by Tiroler Wissenschaftsfonds from 2012 to 2014 and by the Tyrolean Health Fund from 2014 to 2017 and was finally adopted into regular service in March 2017. T Egelseer-Bründl was supported by the Landesinstitut für Integrierte Versorgung, Tirol.

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