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Heart failure clinic in a community hospital improves outcome in heart failure patients

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Summary

Principles: Heart failure is associated with a grim prognosis. Disease management programmes can improve prognosis in heart failure patients but the applicability to the general population remains limited. We aimed to compare the outcome, pharmacological therapy, and quality of life in unselected heart failure patients from a community hospital area who were managed either in the heart failure clinic or who received the usual care.

Methods and results: We followed 115 patients receiving care in the heart failure clinic (n = 50) or the usual care (n = 65) for at least twelve months. During the follow-up of 561 (463, 701) days significantly less patients from the heart failure clinic were rehospitalized due to heart failure or died (42% *vs* 65%). Assignment to the heart failure clinic (Hazard ratio [HR] 0.39, 95% Confidence interval [CI] 0.20–0.75), New York Heart Association class (HR 2.32, 95% CI 1.22–4.41), and systolic blood pressure (HR 0.98, 95% CI 0.96–0.99) independently predicted occurrence of heart failure rehospitalisations or death. At the end of the follow-up patients from the heart failure clinic received more optimal pharmacological therapy and reported better quality of life.

Conclusions: Patient management in the community hospital heart failure clinic reduced the incidence of heart failure rehospitalisation or death with further benefits in terms of pharmacological therapy and quality of life.

Key words: disease management; mortality; heart failure rehospitalisations; pharmacological therapy; quality of life

Introduction

Despite important advances in the management of heart failure (HF) over the last two decades [1, 2] the prognosis of these patients remains grim [3, 4]. Both short and long-term mortality exceeds the rate observed for most cancers [5]. Next to that, HF is associated to frequent hospitalisations [6], poor quality of life [7], and exceedingly high management costs [8]. Although several drugs have shown beneficial effects in landmark clinical trials and are included to European Society of Cardiology guidelines [2], the implementation in everyday clinical practice remains below optimal [9].

The complexity and burden of HF have led to the development of disease management programmes [10]. Recent meta-analyses provided sufficient evidence that disease management programmes can reduce HF rehospitalisations and costs [11, 12] and also mortality, when specialized follow-up by a multidisciplinary team is employed [13]. However, most of the studies were performed in tertiary care hospitals or specialised centres hence the applicability to the general population remains limited. Only recently an outpatient HF disease management programme designed for primary care was reported [14], while data on community hospitals is still lacking.

In the present study we aimed to compare the number of HF rehospitalisations, mortality, pharmacological therapy, and quality of life in unselected patients from a community hospital area who were managed either in the HF clinic or who received the usual care (UC).

No financial support declared.

Methods

Study design and sample

We prospectively followed 115 patients with symptoms and signs of HF and left ventricular ejection fraction – LVEF <45%. They were previously hospitalised at our community hospital that provides general medical and non-invasive cardiology procedures to a mostly rural population of approximately 125,000 inhabitants. For 12 months, as of March 2002, a discharge physician could refer patients who were discharged, to our clinic. A control group receiving usual care (UC) was formed retrospectively from other patients discharged from our hospital in the same time period. The subjects were matched for age (<55 years: 12 and 14 subjects; 56–65 years: 8 and 11 subjects; 66–75 years: 13 and 19 subjects; >75 years: 17 and 21 subjects) and gender. The number of controls in each stratum was adjusted to age and gender distribution among the patients receiving care in the HF clinic. The final sample included 50 patients in the HF clinic group and 65 patients in the UC group, who were followed for at least 12 months. The hospital ethics committee approved the study protocol.

Interventions

The HF clinic medical staff included a physician and a nurse, who are specialized in the management of HF patients. Other specialists (eg nephrologists, diabetologist, and psychiatrist) and medical profiles (dietician, physiotherapist) were available at our hospital. The HF physician had free access to echocardiography and other non-invasive cardiology procedures. Management in our HF clinic consists of several standardised interventions by HF clinic medical staff. During a first visit patients and their relatives or care providers had an introductory consultation with the physician about the basics of HF, aetiology, and clinical presentation, non-pharmacological measures (dietary restrictions, weight control, daily fluid intake, physical activity, and immunisation). Additional ten-minute-nurse sessions about communication, action plan, life style changes, warning signs of worsening or deterioration, and first steps of self-management were part of subsequent visits. During the working hours patients had a possibility for telephonic advice about the clinical condition or drug regimen. Patients also received the leaflet with the concise information about the disease and action plan until the next appointment. Appointments were scheduled according to the clinical presentation and need for titration of the drugs. Except in case of known contraindication, adverse drug reaction or recorded drug intolerability, the drugs were initiated/continued and uptitrated to the recommended daily doses while diuretic daily doses were adapted to the individual patient.

The UC was defined as any management outside the HF clinic. Those patients did not receive specific or standardised HF intervention. Majority of patients were managed by their primary care physicians and some of them by their internists or cardiologists.

Study outcomes and data collection

Primary outcome of the study was HF rehospitalisation or death from any cause. Survival status and occurrence of the HF rehospitalisations for the HF clinic group was obtained prospectively during the visits to the HF clinic and from the medical records. For the UC group the data of interest was derived from the medical records. Survival status of all patients was cross-checked with the local authorities and the State Registry of Death. In addition, all survivors were invited for a control visit in the HF clinic between May and June 2004.

Secondary outcomes were pharmacological therapy and quality of life. Data were obtained at baseline and during the control visit in the HF clinic. The nurse evaluating the quality of life parameters and NYHA class at the end of the follow-up was blinded to the group assignment. Pharmacological therapy was estimated by percent of patients, prescribed with the drug and by prescribed daily dose. Daily doses of different drugs from the same drug class were compared. Enalapril and carvedilol were selected as the reference drugs for ACE inhibitors and beta blockers, respectively [2]. Only patients treated with ACE inhibitors or beta blockers were included to this evaluation, ie patients not receiving these drugs were omitted from the analysis. Equivalent doses of other drugs from these drug groups were calculated by multiplying the daily dose by a factor between target daily doses of used drug and target daily dose of enalapril or carvedilol, respectively (ie 4/20 in case of perindopril and 10/50 in case of bisoprolol). If a range was given for a certain drug then the upper limit was used for the equivalent daily dose calculation (i.e. 10/20 in case of ramipril). Quality of life was assessed by New York Heart Association (NYHA) class and Minnesota Living with Heart Failure Questionnaire (MLHFQ). Additionally, patients rated their perception of quality of life and of health on a seven-category descriptive scale from 1 (best) to 7 (worst), which was already used in a large scale pan European survey [15]. Glomerular filtration rate was estimated using the Cockroft Gault equation [16].

Statistical methods

Continuous variables are described as median values with corresponding 25th and 75th percentiles. Categorical variables are reported as absolute numbers and proportions.

Event-free survival defined as absence of primary end-point was estimated by the Kaplan-Meier curves. Cox proportional hazard model was used to study the relationship between the assignment to HF clinic and the primary end-point. Predefined clinically relevant covariates were forced into the model to determine independent predictors of primary end-point after adjustment for relevant covariates. We report hazard ratios (HR) and corresponding 95% confidence intervals (CI). Data collection and all calculations were made using SPSS 11.0 (SPSS Inc, 2001, USA).

Results

The baseline characteristics of 115 included patients according to the type of outpatient care are presented in table 1. In both groups elderly males prevailed. Hypertension, atrial fibrillation, and ischaemic heart disease were the most common co-morbidities, present in at least 39% of the patients. Groups were similar in most compared clinical and demographic characteristics except for systolic blood pressure, glomerular filtration rate, and haemoglobin level. The median follow-up

Table 1

Baseline demographic and clinical characteristics. Values are median (25th, 75th percentile) or number (%) of patients.

	Heart failure clinic (n = 50)	Usual care (n = 65)
Age [years]	71 (56, 76)	73 (64, 79)
Men	33 (66%)	42 (65%)
Co-morbidities		
Ischaemic heart disease	21 (42%)	24 (37%)
Myocardial infarction	14 (28%)	17 (26%)
Arterial hypertension	30 (60%)	33 (51%)
Diabetes Mellitus	13 (26%)	20 (31%)
Chronic renal disease	18 (36%)	27 (42%)
Hypercholesterolaemia	20 (40%)	21 (32%)
Atrial fibrillation	26 (52%)	33 (51%)
Stroke or transitory ischaemic attack	3 (6%)	3 (5%)
Pulmonary rales	34 (68%)	47 (72%)
Peripheral oedema	42 (84%)	53 (81%)
Heart rate [beats/min]	82 (77, 90)	80 (73, 90)
Systolic blood pressure [mm Hg]	131 (120, 144)	124 (111, 137)
Diastolic blood pressure [mm Hg]	80 (76, 84)	78 (72, 82)
Blood urea nitrogen [mmol/L]	7.6 (5.9, 9.1)	7.7 (6.2, 10.0)
Creatinine [µmol/L]	91 (80, 109)	102 (81, 121)
Glomerular filtration rate [ml/min]*	69 (52, 84)	57 (43, 83)
Glomerular filtration rate <60 ml/min	19 (38%)	36 (55%)
Sodium [mmol/L]	139 (138, 141)	139 (136, 142)
Haemoglobin [g/L]	142 (134, 152)	131 (120, 142)
Total cholesterol [mmol/L]	5.1 (4.3, 5.7)	4.7 (3.9, 5.7)
Left ventricular ejection fraction [%]	40 (35, 43)	40 (35, 42)
NYHA class at baseline	3 (3, 3)	3 (2, 3)
Length of stay [days]	10 (9, 13)	13 (9, 16)
Pharmacolgical treatment at discharge		
ACE inhibitors	47 (94%)	58 (89%)
Beta blockers	20 (40%)	23 (35%)
Spironolactone	27 (54%)	38 (58%)
Furosemide	42 (84%)	55 (85%)
Digoxin	30 (60%)	33 (51%)
Aspirin	13 (26%)	16 (25%)
Warfarin	19 (38%)	26 (40%)
Statins	14 (28%)	16 (25%)
Nitrates	11 (22%)	9 (14%)
Calcium antagonists	6 (12%)	11 (17%)

NYHA – New York Heart Association; ACE – angiotensin converting enzyme
* calculated using the Cockroft Gault equation (16).

Table 2

Hazard ratios with 95% confidence intervals for the evaluation between the baseline variables and occurrence of heart failure rehospitalisation or death during the follow-up.

	Hazard ratio (95% Confidence interval)
Heart failure clinic	0.39 (0.20–0.75)
Left ventricular ejection fraction [%]**	0.99 (0.94–1.04)
New York Heart Association class*	2.32 (1.22–4.41)
Heart rate [beats/min]**	1.00 (0.98–1.02)
Systolic blood pressure [mm Hg]	0.98 (0.96–0,99)
Haemoglobin [g/L]**	0.99 (0.97–1.01)
Cholesterol [mmol/L]*	0.94 (0.76–1.16)
Creatinine [µmol/L]**	1.00 (0.99–1.01)

* Hazard ratio expresses the change in risk for an increase in 1 unit
** Hazard ratio expresses the change in risk for an increase in 10 units

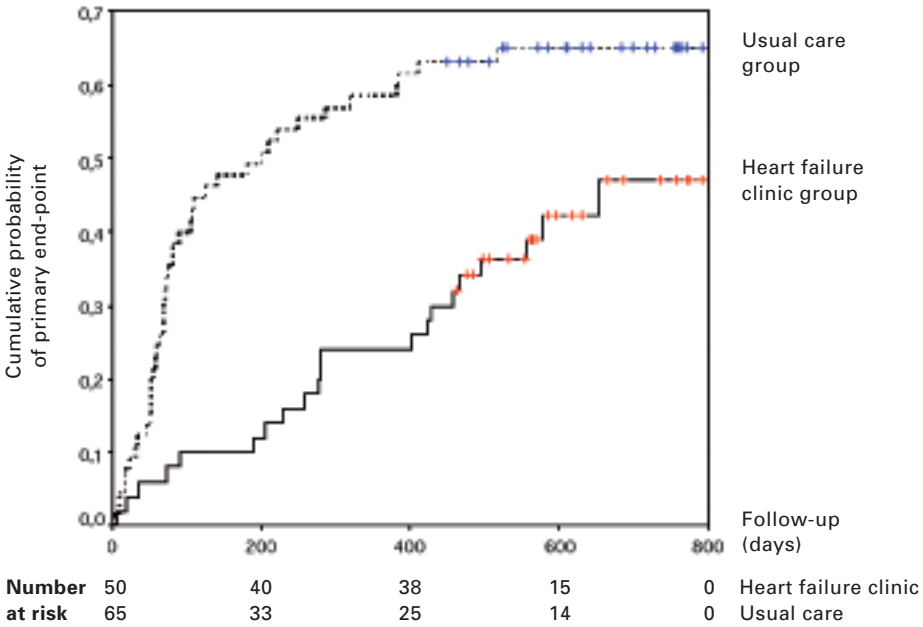

Figure 1
Cumulative probability of heart failure rehospitalisation or death according to the type of care.

time was 596 (498, 751) days for the HF clinic group and 519 (378, 694) days for the UC group. Median number of visits in the HF clinic group was higher than in the UC group (6 [5, 8] times *vs* 3 [2, 6] times). Control visit at the end of follow-up was attended by all 82 survivors, 42 from the HF clinic group and 40 from the UC group.

During the follow-up, 21 (42%) patients from the HF clinic and 42 (65%) patients form the UC group reached the primary end-point. The Kaplan Meier curves showed that the patients from the HF clinic were less likely rehospitalized due to HF or died during the follow-up of 561 (463, 701) days (figure 1). As shown in table 2, the risk of HF rehospitalisation or death was associated with treatment in HF clinic, NYHA class, and systolic blood pressure.

During the follow-up significantly less patients from the HF clinic group were hospitalized due to HF (34% *vs* 55%). The total number of HF rehospitalisations was also lower in the HF clinic group (26 *vs* 64). The patients from the HF clinic group spent less days in the hospital (238 days *vs* 1240 days) and the overall hospital stay per hospitalized patient was also shorter (11 [7, 16] days *vs* 25 [20, 46] days). We registered 8 deaths in the HF clinic group compared to 25 deaths in the UC group at the end of follow-up. Patients most often

Table 3
Pharmacological treatment and quality of life at the end of follow-up. Data are presented as number of patients (%) and median (25th and 75th percentile).

	Heart failure clinic (n = 42)	Usual care (n = 40)
Pharmacological treatment		
ACE inhibitors or ARB's	42 (100%)	36 (90%)
Enalapril equivalent daily dose [mg]	20 (10, 20)	10 (5, 20)
Beta blockers	39 (93%)	19 (48%)
Carvedilol equivalent daily dose [mg]	50 (25, 50)	12.5 (6.25, 25)
Spironolactone	30 (71%)	25 (63%)
Daily dose [mg]	25 (25, 25)	25 (25, 25)
Any diuretic	37 (88%)	37 (93%)
Furosemide	28 (48%)	34 (85%)
Daily dose [mg]	20 (20, 40)	20 (13, 40)
Digoxin	5 (12%)	17 (43%)
Aspirin	14 (33%)	11 (28%)
Anticoagulants	16 (38%)	15 (38%)
Statins	8 (19%)	13 (33%)
Nitrates	1 (2%)	12 (30%)
Calcium antagonists	1 (2%)	5 (13%)
Quality of life		
NYHA class	2 (2, 3)	3 (3, 3)
MLHFQ	30 (21, 39)	46 (34, 55)
Quality of life	4 (3, 5)	4 (4, 5)
Quality of health	4 (3, 5)	4 (4, 5)

ACE – angiotensin converting enzyme; ARB – angiotensin receptor blocker;
NYHA – New York Heart Association; MLHFQ – Minnesota Living with Heart Failure Questionnaire

died due to sudden cardiac death (3 patients in the HF clinic group and 8 patients in the UC group), followed by advanced HF (2 patients and 7 patients, respectively), acute coronary syndrome (2 patients and 4 patients, respectively) and non-cardiac or undetermined cause of death (1 patient and 6 patients, respectively).

At the end of the follow-up the patients from the HF clinic and the UC group were treated with a similar number of drugs (6 [5, 6] *vs* 6 [5, 7]). Table 3 summarizes the proportions of patients treated with individual drugs. More patients from the HF clinic received ACE inhibitors (98% *vs* 80%) and beta blockers (93% *vs* 48%) while less patients received furosemide (48% *vs* 85%). All parameters of quality of life assessment were better in the patients from the HF clinic (table 3). Fewer patients from the HF clinic were in the NYHA class III or IV (43% *vs* 82%). The patients from the HF clinic evaluated a higher quality of life and a better quality of health on a seven-category descriptive scale and achieved lower MLHFQ score. Several significant differences in the self-care behaviour were detected, favouring the management in the HF clinic. Those patients more frequently reported to be able to adjust the diuretic dose according to the body weight (64% *vs* 40%), daily weighing (57% *vs* 28%), reduction of dietary salt (83% *vs* 60%), and water intake (81% *vs* 58%).

Discussion

This study showed significant reduction of HF rehospitalisations or mortality among patients managed in the community hospital HF clinic when compared to those receiving UC.

The better outcomes for the patients managed in the HF clinic were present early and remained significant throughout the study. Our study is one among a few studies that demonstrated the reduction of mortality in patients receiving either care in the specialised HF outpatient clinic or a specific HF intervention [16–20]. Assignment to an HF clinic proved to be an independent predictor of better outcome, which is consistent with observations by Stewart [19], Azevedo [17], and Atienza [16]. Further independent predictors of event free survival were lower NYHA class and higher systolic blood pressure. Together with borderline significance for creatinine and haemoglobin level, and heart rate one can speculate that the outcome was worse in patients with relevant co-morbidities. Our results are in line with previous observations showing the prognostic importance of anaemia [22], renal dysfunction [23], advanced NYHA class, and low blood pressure [24]. Early separation of the survival curves could also reflect some important differences in the baseline variables. Nonetheless, results of the multivariate analysis confirmed the prognostic value of the HF clinic management, probably reflecting both pharmacological and non-pharmacological management, which became evident during the follow-up.

Next to the improved survival we were able to demonstrate the clear benefit in terms of reduced HF rehospitalisation rate, total days in hospital, and number of days in hospital per patient. Next to the better outcome for the patient this also represents an important issue for the health care system and the available budget. Hospitalisations present the bulk of the HF management costs [8] and savings due to reduction of readmissions more than exceed the funds needed for this kind of management [25].

The patterns of pharmacological therapy differed significantly between the compared groups of patients. Visits in the HF clinic allow frequent assessment of pharmacological therapy and clinical status by the HF specialists, who can adjust specific drug treatment and daily dose to the individual patient. Although pharmacological therapy was extensively investigated in the landmark studies [2] it did not attract much of the investigators interest in the specific HF programmes. However, our study and one recent trial [26] clearly demonstrated that intervention in an HF clinic is associated to more optimal prescription and titration patterns, especially in case of beta blockers.

A significant difference in all parameters of quality of life, assessed by the physician or by the patient, reflected intensive educational and other efforts in the HF clinic. The seven-category descriptive scale is not a validated instrument but due to its simple use it could be easily employed in the everyday clinical practice. Nonetheless, the difference in NYHA class and MLHFQ score also favoured the HF clinic group, likely due to the specific education patients received during the management. Quality of life represents an important issue for the HF patients and for some of them it represents the final goal of our management programmes. In patients with advanced stage HF or in terminal HF patients we should be able to add life to years and not only to prolong life. In this context the role of nurses involved in specialised HF management programmes is noteworthy [27]. Non-pharmacological measures are one of the HF treatment cornerstones. Specific education of the patients enables implementation of self-management strategies in everyday life. However, the patient's knowledge is only the basis and we have to ensure that patients have access to the needed equipment (eg weighing scale) and the necessary skills to interpret the results [28].

The non-randomised design represents the primary limitation of this study. Additionally, the

retrospective formation of the control group could cause selection bias. However, patients from both groups were well matched in all demographic and clinical characteristics, which were mainly consistent to previously reported patient characteristics from our hospital [29]. Of some concern is also the non-controlling for the natriuretic peptide level, which is the strong prognostic indicator in HF patients [30]. At the time of the study the natriuretic peptide testing was not available in our hospital, which probably resembles the current clinical practice for most of the HF patients across Europe. The medication patterns were assessed only at the end of the follow-up and not prior to primary endpoint. With regard to the demonstrated better outcome in patients treated with neurohormonal antagonists (1) we assume that only a moderate proportion of patients who reached the primary end-point were actually receiving those agents. The potential bias therefore would be conservative as the event-free patients are more likely to be treated with appropriate drugs. Another issue is the Hawthorne effect, which is well described in patients who have more contact with the medical staff. They could be prone to report higher quality of life to show the appreciation for the care they have received [31]. Nevertheless, our results are consistent with results from several other reports using similar design and sample size [10]. We believe number of included patients did not affect the observed results as most of HF disease management programmes studies include 100 to 200 patients and have demonstrated comparable outcomes [9].

In conclusion, management in the community hospital HF clinic seems to improve the outcome in HF patients despite some clinically relevant baseline characteristics. Further benefit in terms of pharmacological therapy and quality of life was also observed.

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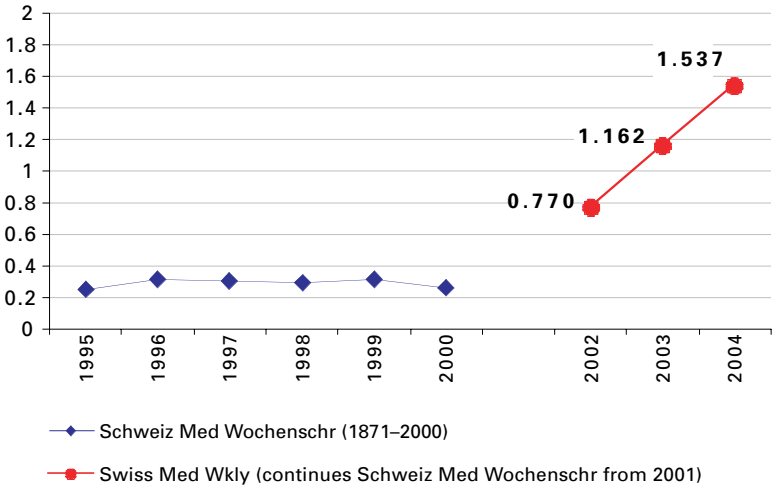

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