

Review

Non-compliance in patients with heart failure; how can we manage it?

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Received 4 September 2003; received in revised form 19 February 2004; accepted 20 April 2004

Available online 4 August 2004

Abstract

Background: Because of the improvement of the pharmacological and non-pharmacological treatment in heart failure (HF) patients, the HF related therapeutic regimen is becoming more complicated. Non-compliance with this regimen can result in worsening HF symptoms, sometimes leading to hospitalisation. **Aims:** The aims of this systematic literature review are (1) to describe the consequences of non-compliance in HF patients; (2) to summarise the degree of compliance in the various aspects of the therapeutic regimen; and (3) to review interventions that are recommended to improve compliance in HF patients. **Methods:** A literature search of the MEDLINE and CINAHL database from 1988 to June 2003 was performed. Studies on compliance with life style recommendations according to the HF Guidelines of the European Society of Cardiology and the American Heart Association/American College of Cardiology were included. **Conclusion:** Non-compliance with medication and other lifestyle recommendations is a major problem in patients with HF. Evidence based interventions to improve compliance in patients with HF are scarce. Interventions that can increase compliance and prevent HF related readmissions in order to improve the quality of life of patients with HF need to be developed and tested.

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Keywords: Patient-compliance; Adherence; Heart failure

1. Introduction

Compliance has long been recognised as an important issue in health-care. In 1976, Sackett and Haynes published an important standard work on compliance in health care [1]. Nowadays, compliance still is an important problem in chronic disease in general [2,3] and it is also relevant in patients with HF [4–8]. Improvement of the medical options for HF patients has for most patients resulted in a complicated regimen.

According to the HF guidelines of the European Society of Cardiology (ESC) [9] and the American Heart Association/American College of Cardiology (AHA/ACC) [10] multiple medication (ACE-inhibitors, diuretics, beta-blockers, spironolactone, digoxin) are beneficial for HF patients and should therefore be prescribed. Non-pharmacological life style changes such as fluid- and sodium-restriction, daily weighing, adjustment of activity, vaccination against influenza, smoking cessation and limitation of the amount of alcohol are requested. Several authors recognise the prob-

lem of non-compliance in HF, however, most publications focus mainly at compliance with medication and overlook other important lifestyle changes. Additionally, there is limited insight in which interventions are tested and are successful in improving patient compliance.

This systematic literature review addresses (1) the consequences of non-compliance in HF patients; (2) the degree of compliance in the various aspects of the therapeutic regimen; and (3) interventions to improve compliance in HF patients. Although there are reviews on compliance in cardiovascular disease [11] and heart failure [12], our review focuses more on the different aspects of compliance with the heart failure related regimen (for example, compliance with medication, diet and daily weighing) and on factors related to non-compliance.

2. Method

A literature search of the MEDLINE and CINAHL databases from 1988 until June 2003 was performed. The term ‘(congestive) heart failure’ was used combined with the terms ‘(patient)compliance’ and ‘(non)adherence’.

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Articles that were included are descriptive as well as experimental studies on adult HF patients that measured compliance with life style recommendations mentioned in the ESC and AHA/ACC guidelines. Studies in English and German language were included. Studies on guideline adherence by health care providers were excluded. Additional articles were found through examination of references from articles to ensure that all relevant studies were included. Two researchers were involved in selecting and reviewing the articles. A total of 48 articles were thus traced and selected for this overview.

3. Definition and measurement of compliance

Compliance can be defined as ‘the extent to which a persons’ behaviour (in terms of taking medication, following diet or executing life style changes) coincides with the ‘clinical prescription’ [1]. Although other terms are used to describe the same phenomenon (for example adherence, therapeutic alliance and concordance), the term compliance is widespread despite the negative connotation of the one-way-direction from the describing health care provider to the obeying patient. Today, the term compliance is often used in a different way, and is related to the situation where the relationship between patient and health care provider is based on respect and collaboration [13].

To assess compliance, patient interviews or self-report questionnaires are mostly used. Other instruments are pill count, Medication Event Monitoring System (MEMS), measurement of the serum medication concentration or serum ACE activity, interview of the health care provider, chart review and patient diaries.

4. Results

4.1. Consequences of non-compliance in HF patients

Increase in the complexity of the treatment regimen is expected to result in a decrease in patient compliance [1]. Non-compliance with medication, diet or fluid restriction decreases the efficacy of the treatment prescribed and exposes the patient to clinical destabilisation, which can lead to increased HF symptoms. Stewart et al. [14] described the relationship between non-compliance with medication and fluid restriction and clinical instability. Eleven retrospective studies have reported worsening HF, the causes of worsening HF and the relationship with non-compliance (Table 1). In nine of these studies, the most commonly identified cause of HF worsening was non-compliance with medication and diet; in 21–64% of patients, non-compliance was the precipitating factor of HF exacerbation, sometimes leading to hospitalisation [15–23]. Two other studies reported arrhythmia’s [24]

and cardiac ischemia [25] as the most important reasons for worsening HF.

In a prospective cohort study ($N=431$) higher readmission rates, more hospitalisation days and a lower EF after 6 years were found in HF patients who were non-compliant with digoxin compared to patients who were compliant with the prescribed digoxin [26]. Since the follow-up period was extremely long, other factors such as change in disease severity may have influenced the outcomes.

Other important identified causes of HF worsening are uncontrolled hypertension (2–44%) [15,18,19,21,22,25], cardiac arrhythmia’s (6–29%) [15,18,19,22,24,25], cardiac ischemia (5–33%) [18,19,21,22,24,25] and (pulmonary) infection (6–23%) [15,18,21,24,25]. Inadequate treatment such as insufficient diuretic therapy, treatment with negative inotrope medication (such as verapamil and diltiazem) and a lack of modification of treatment after reporting worsening symptoms contributed to HF worsening in 12–44% of the patients [15,18,19]. The authors remark that some factors such as arrhythmia’s and ischemia are difficult to prevent while others such as inadequate medication or non-compliance probably can be influenced.

4.2. Compliance rates in HF patients

Studies on compliance with medication, diet, daily weighing, daily activity, restriction of alcohol, smoking cessation, influenza vaccination and delay in treatment seeking behaviour in HF patients are successively described. Factors that are related to compliance can be divided into patient related factors (such as age and gender), regimen related factors (for example the complexity of the regimen) and factors related to the health care provider or to the health care system (such as the number of contacts with a health care provider).

4.2.1. Compliance with medication

Medication is the cornerstone of the treatment of HF patients nowadays. The most important drugs that are recommended for HF patients according to the ESC and AHA/ACC guidelines are ACE-inhibitors, diuretics, beta-blockers, spironolactone and digoxin. Compliance with medication is measured in several ways in various patient populations, which makes it difficult to compare different studies and partly explains the variation in compliance rates in descriptive studies (Table 2). Monane and colleagues [8] described compliance rates in HF patients who were treated with digoxin. They found that only 10% of the patients were fully compliant with digoxin during a year. This low compliance rate is alarming, however, most studies describe compliance rates approximately 70% [4,27–33].

In a study with in-depth interviews in 22 HF patients Cline [4] reported that half of the patients ($n=11$) could not recall the correct dose of the prescribed medication and 14 patients could not remember the correct time for

Table 1
Studies on factors that contribute to worsening HF

	Ghali et al. [15]	Vinson et al. [17]	Bushnell et al. [20]	Wagdi et al. [18]	Opasich et al. [24]	Chin et al. [25]	Happ et al. [23]	Michalsen et al. [19]	Opasich et al. [21]	Tsuyuki et al. [22]	Buckle et al. [16]
Year of the study	1988	1990	1992	1993	1996	1997	1997	1998	2001	2001	2002
Included patients	<i>N</i> =101	<i>N</i> =161	<i>N</i> =51	<i>N</i> =111	<i>N</i> =304	<i>N</i> =435	<i>N</i> =8	<i>N</i> =179	<i>N</i> =215	<i>N</i> =180	<i>N</i> =116
	59 year	81 year	71 year	76 year	53 year	69%>60 year	76 year	75 year	63 year	63 year	70 year
	46% female	58% female	42% female	41% female	87% female	42%>70 year 53% female	50% female	48% female	23% female	18% female	63% female
Factors contributing to worsening HF ¹ :											
Non-compliance with Medication/diet	64%	33%	42%	47%	15%	21%	62%	42%	21%	29%	62%
Delay in seeking help		20%									
Uncontrolled hypertension	44%			27%		15%		6%	5%	2%	
Cardiac arrhythmia's	29%			14%	24%	8%		6%		13%	
Inadequate treatment ²	17%			44%				12%			
(Pulmonary) Infection	12%			6%	23%	16%			12%		
Inadequate discharge planning		15%									
Lack of social support		21%									
Cardiac ischemia				14%	14%	33%		13%	5%	10%	
Unknown					9%	34%			40%		

¹ Causative factors leading to worsening heart failure in the study population.

² Insufficient diuretic therapy, treatment with negative inotrope medication or lack of modification of medication after worsening symptoms.

Table 2
Compliance with medication (descriptive studies)

Reference	Study population	Instrument	Compliance
Bussey et al. (1988) [33]	15 HF patients with digoxin at the outpatient clinic Mean age 59 27% female	Pill count Interview	≥ 80%
Kruse et al. (1992) [5]	18 HF patients with digoxin + diuretics Mean age 76 50% female	MEMS (digoxin + diuretics)	74%
Monane et al. (1994) [8]	7247 HF patients with digoxin Mean age 77 79% female	Number of days enough digoxin was available	10%
Bennet et al. (1998) [31]	390 hospitalised HF patients Mean age 67 19% female	Chart review	84%
Rogers et al. (1998) [32]	64 HF patients on enalapril Mean age 65 43% female	Proportion of available Enalapril	>75% in 67% of the patients
Cline (1999) [4]	22 HF elderly after readmission for HF Mean age 79 36% female	Interview	73%
Ni et al. (1999) [30]	113 new outpatient clinic HF patients Mean age 51 26% female	Questionnaire	77%
Roe et al. (1999) [29]	869 HF patients on ACE-inhibitor Mean age 60 27% female	Proportion of available ACE-inhibitor	71%
Struthers et al. (1999) [56]	73 HF patients Mean age 71 23% female	Proportion of available ACE-inhibitor	<85% in 34% of the patients
Jaarsma et al. (2000) [39]	128 HF patients Mean age 72 40% female	Heart Failure Self Care Behaviour Scale	88%
Roe et al. (2000) [37]	236 HF patient hospitalised for HF Mean age 71 35% female	Supply of ACE inhibitor divided by number of days	86% (before hospitalisation) 81% (after hospitalisation)
Struthers et al. (2000) [36]	487 HF patients with a previous HF admission Age: 80% >65 48% female	Proportion of available Diuretics	95%
Evangelista et al. (2001) [34]	82 HF patients known on the HF clinic Mean age 54 38% female	Questionnaire	96%
Artinian et al. (2002) [35]	110 HF patients (32 hospitalised; 78 outpatients) Mean age 64 22% female	Questionnaire	93%
Welsh et al. (2002) [27]	57 HF patients treated for HF on the emergency department Mean age 64 54% female	Patient interview	79%
Bohachick et al. (2002) [38]	171 HF patients, known on the HF clinic Mean age 56 30% female	MEMS (ACE inhibitor)	84%
Chui et al. (2003) [28]	42 HF patients treated on the outpatient clinic Mean age 57 40% female	MEMS (diuretics)	72%
Schwarz et al. (2003) [57]	128 HF patients Mean age 77 50% female	Patient interview	99%

taking the medication. It was remarkable in this study that more than three-quarters of patients ($n=18$) took medication that was not prescribed. This concerned medication that should have been discontinued or new medication

prescribed between discharge and the moment of the interview (=30 days after discharge). High compliance rates (96%) are described in a study of young HF patients (mean age 54 years) [34]. Most of these patients were

highly educated and had a strong social support system, which probably influenced compliance rates [34].

Patient-related factors with a positive relationship to compliance with medication in a HF population are previous readmission for HF [8] or for all causes [32], a higher age [8,19,35], a higher NYHA class [35], less chronic co-morbidity [32] and a diagnosis of asthma or COPD [32]. Overall compliance (= compliance with medication, diet and daily weighing) was associated with marital status and patients self-confidence to maintain health status [30].

There are ambiguous outcomes on differences in compliance between races. In some studies, compliance was found to be higher in White American HF patients [35]; in other studies, no differences were found between Black and White HF patients [8]. Educational level and gender correlated significantly with compliance with medication, however, the data are contradictory. In the study of Artinian [35], patients with a lower educational level were more compliant; others found that educational level and compliance with medication were positively correlated [28]. This inconsistency also exists with regard to gender; some studies found that women were more compliant than men [8,36] other studies found inverse data [29,37]. Patients who took their medication regularly (=with the same dose interval) had a higher overall compliance with medication than patients who took their medication with an irregular dose interval [5].

Medication regimen related factors affecting compliance are the amount of medication, the stability of the regimen and the number of daily doses; the more medication, the more daily doses or the more changes in medication, the higher the non-compliance [19,29,38]. In another study, compliance was not influenced by the complexity of the regimen [5]. Factors that are related to the health care system were the number of outpatient visits [29] and the referring physician [29,30]. More contact with the health care provider at the outpatient clinic and referral by a cardiologist was related to a higher medication compliance [30].

4.2.2. Compliance with diet and fluid restriction

According to HF guidelines controlling, the amount of salt in the diet (≤ 2000 mg) is especially relevant in patients with severe HF [9,10] and a fluid restriction of 1500–2000 ml should be recommended in advanced HF patients [9].

Compliance with a sodium restricted diet varies from 50% [39] to 88% [41] (Table 3). The lowest reported compliance rate for fluid intake was 23% [39]. Others found that instead of having to restrict fluids, 38% of all patients thought they had to drink a lot of fluid [30]. Patient-related factors that affected compliance with diet and fluid restriction in HF patients are a better mental and physical health [34], marital status [35] and race [35]. There was no difference in compliance between newly

Table 3
Compliance with sodium restriction and fluid restriction (descriptive studies)

Reference	Study population	Instrument	Compliance
Bushnell et al. (1992) [20]	41 hospitalised HF patients (educated during hospitalisation) Mean age 71 42% female	Interview	56% (sodium)
Bennet et al. (1998) [31]	390 hospitalised HF patients Mean age 67 19% female	Chart review	81% (sodium)
Ni et al. (1999) [30]	41 hospitalised HF patients Mean age 71 42% female	Questionnaire	73% (sodium)
Jaarsma et al. (2000) [39]	128 HF patients Mean age 72 40% female	HF Self Care Behaviour Scale	50% (sodium) 23% (fluid)
Evangelista et al. (2001) [34]	82 HF patients, known on the HF clinic Mean age 54 38% female	Questionnaire	71% (sodium)
Carlson et al. (2001) [41]	139 HF patients Mean age 69 47% female	Patient interview Questionnaire	88% (sodium)
Artinian et al. (2002) [35]	110 HF patients (32 hospitalised; 78 outpatients) Mean age 64 22% female	Questionnaire	43% (sodium) 37% (fluid)
Welsh et al. (2002) [27]	57 HF patients treated for HF on the emergency department Mean age 64 54% female	Patient interview	71% (sodium)
Schwarz et al. (2003) [57]	128 HF patients Mean age 77 50% female	Patient interview	75% (sodium)

diagnosed and ‘experienced’ patients with HF [41]. Compliance with self-care behaviour (including following diet) was significantly correlated with knowledge [30]. After controlling for knowledge score by multiple regression analyses, poor compliance in this study was associated with being unmarried, lower self-efficacy and no prior hospitalisation.

4.2.3. Compliance with daily weighing

Daily weighing is an important instrument for the detection of worsening HF. According to guidelines patients with HF are advised to weigh themselves daily and in case of a sudden unexpected weight gain, alert a health care provider or adjust their dose of diuretics [9,10].

Compliance with daily weighing ranged from 12% [20] to 75% [42] (Fig. 1). Although 87% of the patients had weighing scales, approximately 40% or less weighed themselves regularly [19,20,39]. Sulzbach et al. [43] found that 40% of the patients weighed themselves daily and 23% two to five times a week. Only 7% of the patients did not weigh themselves at all.

Although in one study, 70% of the patients said that they were told to weigh themselves, 33% of the patients did nothing when weight increased [43]. Seventy-seven percent of the patients did not warn the doctor about weight gain [39] and 50% rated sudden weight gain not as important [41].

Patient related-factors associated with poor compliance were being unmarried, a lower self-efficacy, a lack of knowledge on HF self-care and no prior hospitalisation [30]. Patients with a history of HF showed a more adequate response to sudden weight gain than patients newly diagnosed with HF [41].

4.2.4. Compliance with recommendations on activity and rest

HF patients in a stable condition should be encouraged to carry out daily physical and leisure time activities that do not induce symptoms [9,10]. Advice about physical

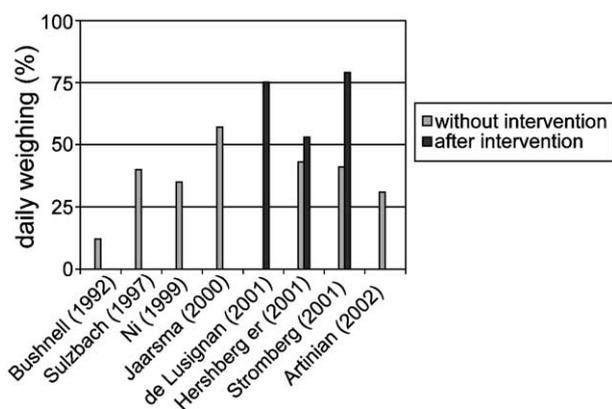


Fig. 1. Compliance with daily weighing in descriptive and intervention studies (without and after intervention).

activity and the balance between activity and rest is nowadays part of many HF management programs. Despite this advice, the recommendations are not followed by 41–58% of patients [30,34,35,39,41]. Thirty percent of HF patients reported that they had stopped exercising after they were diagnosed with HF [41]. Twenty-three percent of patients did not divide their activities over the day and 18% did not rest during the day [39]. Patients who lived alone, had a higher mental and physical health, had a lower neuroticism score or were newly diagnosed with HF were more likely to be compliant with advice on activity and rest [34,35,41].

4.2.5. Compliance with other life style recommendations in HF patients

Excessive alcohol intake and smoking are strongly discouraged in HF patients because of their negative effects on the cardiovascular system [9,10]. Compliance with limitation of alcohol use varied from 56 to 94% [30,34,35,39,41]. In half of the studies approximately 90% of the patients stated they were non-smokers [30,34,41]. Non-compliance with smoking and alcohol restrictions was significantly related to the number of readmissions [44]. In the HF population, smoking cessation was related to race [35] and marital status [34].

Another recommendation for HF patients, according to guidelines, is vaccination against influenza [9,10]. Artinian [35] assessed compliance with vaccination against the flu and found a compliance rate of 68%. Older patients and women were more consistent in getting a flu shot once a year [35]. White American HF patients were found to be more compliant in getting an annual flu shot than Black Americans [35].

4.2.6. Delay in treatment seeking behaviour

A new issue in the field of compliance research is patient delay in seeking treatment. Delay in treatment seeking behaviour can be described as the amount of time between the first awareness of symptoms and the arrival in the hospital. Although HF patients are advised to seek help in case of worsening symptoms, it is difficult to state whether or not they are compliant toward this advice because it is unclear what amount of delay time is acceptable.

A delay time of 3 days or more was common in HF patients [18,45,46], although 28% of the patients waited more than 120 h to seek assistance [46] (Table 4). Twenty-three percent of the patients experienced symptoms for several weeks [18].

Oedema, cough, fatigue and weight gain was all tolerated for a longer time before hospitalisation (median duration 7 days) than dyspnoea (median duration 3 days). It was remarkable that only 5% of the patients reported weight gain as a symptom on admission [45].

Table 4
Delay in treatment seeking behaviour

Reference	Study population	Instrument	Delay
Vinson et al. (1990) [17]	140 hospitalised HF patients Mean age 81 58% female	Medical record review + patient interview	20% readmission due to delay
Wagdi et al. (1993) [18]	111 hospitalised HF patients Mean age 76 41% female	Medical record review + patient interview	72% had a delay of several days
Friedman et al. (1997) [45]	181 hospitalised HF patients Mean age 76 59% female	Medical record review	92% had symptoms 3 days before admission
Evangelista et al. (2000, 2002) [46,58]	753 HF patients from a Veteran hospital Mean age 69 1% female	Medical record review	median delay time 3 days 28% had delay >5 days
Artinian et al. (2002) [35]	110 HF patients (32 hospitalised; 78 outpatients) Mean age 64 22% female	Questionnaire	56% delay in case of swelling of ankles/legs 83% delay in case of weight gain

A shorter delay time was associated with marital status [35] being newly diagnosed with HF [45] or having a previous HF readmission [46].

Predictors of delay were found to be the presence of dyspnoea and oedema, care provided by a primary care provider and a higher NYHA class. The presence of chest pain resulted in a shorter delay time. There was no relation between age and delay time [46].

4.3. Interventions to improve compliance in HF patients

Currently, there are a limited number of studies on interventions to improve compliance in a HF population. Twelve intervention studies in HF patients were found, with compliance as an outcome variable. Randomised and non-randomised studies are described in Tables 5 and 6.

Eight randomised studies described the effect of interventions with a component of education and counselling on the improvement of compliance in HF patients (Table 5). Patients were educated and counselled by a nurse at the HF clinic or in a home-based intervention in three randomised studies [13,47,48]. Although these three interventions differed in intensity, disciplines involved and place of the intervention (HF clinic, at home or in combination with contact by telephone), all were at least partly effective in the improvement of compliance.

A multidisciplinary intervention with emphasis on education and counselling during hospitalisation, at home and by telephone follow up was effective in the improvement of medication compliance [48]. A significant improvement in daily weighing after 12 months and compliance with fluid restriction after 3 months was achieved in an intervention with a nurse led HF clinic [13]. In this study no significant difference was found in compliance with fluid restriction between the intervention group (50%) and control group (28%) after 12 months. In

an intervention with frequent contact at the HF clinic and by telephone there was an increase in patients who complied with their diet [47].

In three other randomised studies, a pharmacist educated patients on their medication regimen in one or more sessions [7,49,50]. In all studies, there was a significant increase in compliance with medication in the intervention group. In one study, however, there was no significant difference in self reported compliance after 6 months but in a small population ($n=23$) 10 patients in the intervention group against three in the control group were compliant in filling in their prescriptions from the pharmacy [50].

Other successful randomised studies consist of mailing educational materials [40] and having daily phone or video contact with HF patients to remind them to take their medication as prescribed [6].

The results of the randomised studies described above are sometimes reported in non-randomised studies, however, in some interventions compliance remains low even after comprehensive education (Table 6).

A nurse led intervention at the HF clinic, resulted in an increase in knowledge on sodium restriction, but only 35% of the patients always avoid salty foods and 52% of the patients read labels when buying food [51]. In the study of West et al., patients were educated about HF and the HF related regimen during a visit to the HF clinic and during frequent follow-up by telephone over 6 months. This study with intensive contact with a nurse showed a decrease in self-reported sodium intake in patients who received structured education on their diet [52]. Education on diet and sodium restriction by a dietician resulted in a significant decrease of fluid and sodium intake [53]. In a small study, an intervention using home telemonitoring in HF patients, resulted in compliance with daily weighing in 75% of the patients [42].

Table 5
Randomised intervention studies on the improvement of compliance in HF patients

Author	Study population	Involved disciplines	Intervention/design	Duration/intensity of the intervention	Compliance before intervention	Compliance after intervention
Rich et al. (1995) [48]	156 hospitalised HF patients Mean age 79 67% female	Nurse, geriatric cardiologist, dietician, social worker, Pharmacist, home health care	Multidisciplinary intervention with; early discharge planning, education and counselling, medication review, follow-up (homevisit + phone) (randomised clinical trial)	30 days (during hospitalisation and after discharge)	Not measured	co: 81% (med.) int: 88% ($P < 0.001$)
Goodyer et al. (1995) [7]	100 stable HF patients Mean age 85 73% female	Pharmacist	Counselling on medication (randomised clinical trial)	3 months (four contacts at the pharmacy)	co: 49% (med.) Int: 61% (NS)	co: 51% (med.) int: 93% ($P < 0.001$)
Serxner et al. (1998) [40]	109 discharged patients Mean age 71 52% female	–	Mailing educational materials (randomised clinical trial)	Every 4 weeks (4 times)	70%	co: 40% (med.) int: 70% ($P < .05$)
Fulmer et al. (1999) [6]	50 community dwelling HF Patients Mean age 74	Research assistant	Daily telephone reminder or daily videophone reminder (randomised clinical trial)	6 weeks	co: 81% (med.) int.1: 76% int.2: 82% (NS)	co: 57% (med.) int.1: 74% int.2: 84% ($P < 0.05$)
Varma et al. (1999) [50]	23 elderly patients Age > 65	Pharmacist	Education on HF, treatment, lifestyle changes by a pharmacist during (post-test only, randomised)	During hospitalisation	not measured	co: 30% (med) int: 78% ($P = 0.039$)
Stromberg et al. (2001) [13]	106 HF patients Mean age 79 40% female	Nurse	Education and counselling on HF, diet, medication, self-management, symptom recognition, psychosocial problems. Follow up at the HF clinic and by phone (randomised clinical trial)	12 months (visit to HF clinic 2 weeks after discharge, phone contact)	28% (fluid) 41% (weighing)	50% (fluid) 79% (weighing) ($P = 0.002$)
Bouvy et al. (2002) [49]	152 patients admitted for HF or from HF clinic Mean age 70 43% female	Community pharmacist	Counselling on medication (randomised clinical trial)	6 months (monthly contact at the pharmacy)	Not measured	co: 94% (med) int: 98% ($P < 0.05$)
Kasper et al. (2002) [47]	200 HF patients with a high readmission risk Mean age 62 40% female	Nurse, cardiologist, primary care physician	Education and counselling on HF, diet, medication, symptoms, activity. Optimise medication. Follow up at HF clinic or at home and by telephone (post-test only, randomised)	6 months (frequent visits at HF clinic + phone contact)	Not measured	co: 45% (diet) int: 69% ($P = 0.002$)

Table 6
Non-randomised intervention studies on the improvement of compliance in HF patients

Author	Study population	Involved disciplines	Intervention/design	Duration/intensity of the intervention	Compliance before intervention	Compliance after intervention
West et al. (1997) [52]	51 HF patients Mean age 66 29% female	Nurse, cardiologist	Education on HF, medication, diet, physical activity, symptoms, improvement of compliance, optimise medication (pre-post test only)	6 months (one contact at the HF clinic, after that frequent phone contact)	Sodiumintake/day: 3393 mg	Sodiumintake/day: 2088 mg ($P < 0.01$)
De Lusignan et al. (2001) [42]	20 HF patients Mean age 75	Nurse, cardiologist	Telemonitoring to measure weight, BP, pulse (post-test only)	12 months (weekly video contact first 3 months, after that less often)	Not measured	int: 75% (weighing)
Hershberger et al. (2001) [51]	108 new outpatients with HF Mean age 52 27% female	Nurse, cardiologist, social worker	Education and counselling on HF, diet, medication, symptom recognition, improvement of compliance, arrangement of home care when indicated, follow up at the HF clinic, available by phone (pre-post test only)	Depending on the patients needs (visits at the HF clinic, phone contact)	81% (med.) 78% (fluid)	82% (med) (NS) 96% (fluid) ($P < 0.01$)
Kuehneman et al. (2002) [53]	79 HF patients	Dietician	Individualised education on diet and fluid restriction at the outpatient clinic (pre-post test only)	6–9 months baseline and follow-up after 3 and 6–9 months at the outpatient clinic, more often when indicated)	Sodiumintake/day: 2300 mg Fluidintake/day: 2040 ml	Sodiumintake/day: 1800 mg ($P < 0.001$) Fluidintake/day: 1685 ml ($P < 0.001$)

5. Discussion

This review shows that non-compliance with medication and other life style recommendations in HF patients is a major problem, with important consequences for individual HF patients, such as worsening symptoms sometimes leading to readmission. The highest rates of non-compliance are found in diet and fluid restriction, daily weighing and activity and rest. Delay in seeking help when HF symptoms occur is also a major problem in HF patients.

It is difficult to compare the various studies because of differences in the study populations, differences in measurement instruments and differences in interventions that are used to improve compliance.

5.1. Differences in study population

Compliance rates are diverse in the different studies, depending on the study population. Mean age in the included studies varied from 51 to 81 years and representation of women in the studies ranged from 1 to 58%. In the study with the youngest population [34], patients were also highly educated and had a strong social support system, which also influenced the compliance rates.

Differences in the study population also introduce other factors that can explain differences in compliance. Patients older than 85 years old were found to be more compliant than younger patients, which may be due to the fact that very old patients often get more assistance with their medication regimen [8].

Another difference in compliance can possibly be explained by the fact that in some studies only patients who are hospitalised or patients with a previous readmission are included, while in other studies newly diagnosed patients can also participate. Since patients who are hospitalised for HF are possibly more non-compliant than patients who are not hospitalised, results of studies on hospitalised patients are not generalizable to the total HF population.

In addition, in intervention studies at the HF outpatient clinic, patients who don't follow appointments are usually not included in the study resulting in a study population consisting of patients who probably try to follow the provider's instructions [43].

5.2. Differences in the measurement of compliance

Compliance is measured in various ways: medical chart review, patient (in depth) interview, questionnaire and electronic monitoring system. When compliance is measured through patient interview, it may be possible that patients will give socially desirable answers, which can lead to underestimation of the problem. When information on compliance is obtained through chart review, non-compliance rates are probably underreported

because it is not always clear how to recognise non-compliance.

In one study [26] serum digoxin concentration was used to assess compliance. Although at first sight this seems a very objective way to measure compliance, it is also known that serum levels do not always reflect correct medication dosing. The medication event monitoring system (MEMS) registers the date and time of opening of the medication container. Although it is assumed that the time of opening is the time of drug use, actual intake cannot be guaranteed. A restriction of this method can be that patients who are very compliant or have a positive attitude toward medication taking are possibly more motivated to give consent to data-collection with MEMS than patients who are non-compliant. Although measurement with the MEMS itself can have a positive influence on compliance, this effect seems to normalise after a few weeks [6].

In many studies on compliance the questionnaires that are used to measure compliance are not validated. Only the Heart Failure Self Care Behaviour Scale [39] and the Compliance Questionnaire [34] have established content validity.

HF patients are increasingly trained to adjust their dose of diuretics in case of worsening symptoms. This may influence the way compliance with diuretics can be measured and should be interpreted.

5.3. Differences in interventions

There were 12 studies included in this review in which the effect of several interventions on compliance in HF patients was measured. Most of the studies have a component of education and counselling, although the content, the disciplines involved, the place and the duration of the interventions vary widely. The five studies on education and counselling with a nurse involved were all (partly) effective in the increase of compliance. In the study by Rich, education by a nurse combined with a multidisciplinary intervention at home, medication compliance in the intervention group improved 30 days after discharge [48]. In this study, the medication was reviewed and simplified by a pharmacist and a geriatric cardiologist. Another study with a nurse led intervention was successful in the improvement of compliance with daily weighing and fluid restriction 3 and 12 months after discharge, although the improvement in compliance with fluid restriction was not statistically significant after 12 months [13]. According to the authors, the reduced number of patients after 12 months follow-up may have had an impact on the results of self-care behaviour (such as compliance).

Although there was a difference between the 3 studies in the intensity of the counselling on medication by a pharmacist, they were all effective in the improvement of compliance with medication.

There were many different interventions on the improvement of compliance, but from the studies described in this overview it is not clear which part of the interventions were most successful. Moreover we do not know what the optimal dose or intensity of the intervention should be. In interventions on a HF clinic, it is possible that many elderly patients with a more severe illness cannot visit the clinic. For these patients a home-based intervention is probably more effective. There are other interventions, for example calling a patient daily as a reminder to take their medication, which might be effective, but this is not practical or patient-friendly for a longer period.

From this review, it seems that education and counseling might have an important role in improving compliance, however, these outcomes should be interpreted with caution and more detailed information on effective interventions to improve compliance with the HF regimen is needed.

5.4. Implications for practice

Combining advice from descriptive studies and current evidence, the following strategies to improve compliance can be advised;

5.4.1. Patient related strategies

a Targeting patients at risk

Compliance can possibly be improved by targeting specific patient populations with a higher risk of non-compliance, for example, patients who live alone [30], elderly patients [8], patients with more co-morbidity [29] and patients that are recently diagnosed with HF [41].

b Increase in knowledge [7,13,34,39,43,48,49].

c Behavioural strategies

Although knowledge is a necessary condition for the enhancement of compliance, it is not enough to achieve compliance. Other strategies to improve compliance, such as behavioural strategies and improvement of self-efficacy may be necessary [39].

d Self-management

The emphasis on self-care strategies during and after hospitalisation can be important [20]. It is not only important to emphasise the importance of daily weighing, it is probably even more important to explain how a patient should react to weight gain (or weight loss) [39,41,43]. Self-management (for example, a flexible diuretic regimen and knowledge about what to do when symptoms worsen) can be important to prevent worsening HF and to decrease delay time [39,45,46].

e Promotion of social support

When there is no social network around the patient, support can be provided by the HF team, especially by the HF nurse [34,39]. Psychological support and counselling

may improve psychological well-being, self-motivation and compliance [34].

5.4.2. Regimen related strategies

a Simplification of the regimen

Simplification of the medication regimen, the reduction of polypharmacy (if possible) and the use of medication dispensing aids can be helpful for HF patients to improve compliance [4,48].

b Learning to read food labels/attention on multiple diets

Patient education on how to read food labels and to distinguish between high and low sodium foods can help to prevent unintentional non-compliance with diet [54]. Special attention is needed for patients with multiple diets.

5.4.3. Health care provider/health care organisation related strategies

a Reinforcement

Reinforcement, for example at home visits, visits to the outpatient clinic or by telephone can help patients to cope with their therapeutic regimen [4,34,39].

b Prevention of confusion

Prevention of confusion about seemingly contradictory recommendations must be part of the educational plan for HF patients in order to promote compliance [41].

5.5. Implications for further research

It is known that women and older patients are often excluded from HF studies [55]. Since compliance seems to be related to age and gender, it is important to include a spectrum of patients that reflect the real HF population. In order to integrate the results of studies into interventions that will improve compliance of patients with HF, compliance with the therapeutic regimen should be included as an outcome variable. The effect of the interventions suggested needs to be tested in randomised clinical trials. Further research is needed to establish the optimal dose of the interventions required.

It is also a major challenge for researchers to develop valid and reliable instruments to measure compliance in patients with HF.

6. Conclusion

Non-compliance with medication and other lifestyle recommendations is a major problem in patients with HF. Evidence based interventions to improve compliance in patients with HF are scarce. Interventions that can increase compliance and prevent HF related readmissions in order to improve the quality of life of patients with HF need to be tested.

Acknowledgements

Dr Van Veldhuisen is an Established Investigator of the Netherlands Heart Foundation (Grant D97.017). This study was supported by the Netherlands Heart Foundation (Grant 2000Z003).

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