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Clinical Investigation

***Title:* Perceived sexual difficulties and associated factors in patients with heart failure**

***Short Title:* Sexual difficulties in heart failure**

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Abstract

Background: Sexual dysfunction is a common problem of increasing incidence in heart failure (HF) patients. However, there is no knowledge on which demographic, clinical and quality of life aspects are related to difficulties in sexual activity, nor on the course of sexual difficulties in patients with HF.

Methods: Data on sexual difficulties were collected at 1 and 18 months after a HF hospitalization (n=792, mean age 69 ± 12 ; 35% female; mean LVEF $33\% \pm 14$) by the question on sexuality of the Minnesota living with HF questionnaire (MLwHF). Demographic and clinical factors were assessed from medical records and quality of life by MLwHF, RAND-36 and Ladder of Life.

Results: In total 48% (n=380) of the patients perceive difficulties in sexual activity at 1 month after discharge and 70% continued to perceive this at 18 months. Furthermore, 27% of the patients without difficulties at 1 month developed them during follow-up. Living with a partner (OR 3.76, 95% CI 2.58-5.48), younger age (OR 0.96, 95% CI 0.94-0.97), male gender (OR 3.08, 95% CI 2.10-4.43), overall wellbeing (OR 1.13, 95% CI 1.00-1.27), physical (OR 1.06, 95% CI 1.06-1.08) and emotional quality of life (OR 1.07, 95% CI 1.03-1.10) were independently associated with perceived difficulties in sexual activity.

Conclusions: Perceived difficulties in sexual activity are common in HF patients, particularly in younger and male patients, and continue over time. Patients who perceive difficulties in sexual activity report a significant lower quality of life and overall wellbeing than those who do not.

Keywords: Heart failure; quality of life; sexual problems; sexual function; sexual dysfunction

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Heart failure (HF) is a significant health problem affecting the quality of life (QoL) of patients¹. Patients with HF suffer from symptoms such as fatigue and shortness of breath², psychological factors like depression^{1,3}, low functional capacity^{4,5} and also need to manage lifestyle changes⁶. These factors do not only affect overall QoL, but also the intimacy needs of a patient with HF⁷.

It is often expected that among seriously ill patients sexual activity is not important. However, HF patients consider sexual activity in their current condition as an essential aspect of QoL⁸, but symptoms of HF do affect the sexual relationships of HF patients⁹. At least 50% of all HF patients report their sexual activity has reduced or completely ceased as a result of their HF. Furthermore, half of the HF patients have problems with sexual activity caused by erectile dysfunction or orgasmic problems and sexual dissatisfaction⁷⁻¹⁰. The current HF guidelines recommend counseling on sexual activity with both male and female patients and their partners. The given class of recommendation is I, however, the level of evidence is C, which indicates that counseling on sexual activity is suggested to be very important, but not many studies have focused on this subject¹¹. Two small studies examining predictors of decrease in sexual activity in relatively young, and predominantly male HF patients show that worse functional capacity, high NYHA class, the number of medications, diabetes, as well as tobacco and alcohol use contribute to a decrease of sexual activity^{7,12}. Furthermore, HF therapy with beta-receptor blockers, digoxin and thiazide are known to worsen sexual activity¹³. However, it is not known whether these variables are also related to difficulties in sexual activity in an older HF population or specifically in women. Also, studies on sexual problems in patients without a partner are lacking.

Knowledge on the relationship between difficulties with sexuality and QoL is based on a few smaller studies in specific HF study populations and show that better sexual function is

related to a higher overall wellbeing⁹. To appropriately address the importance and effects of difficulties in sexual activity in the lives of all HF patients, including women and elderly, more information is needed on the relationship between QoL and sexual problems.

Although there is a recent growing interest in reporting data on sexual problems of HF patients, current studies have a cross-sectional design without providing insight in sexual problems over time. In case of sexual problems that are assessed at hospital discharge, clinicians may assume that these will disappear spontaneously during recovery. In general there is little follow-up on the course of sexual activity during the trajectory of HF. Only one small study reported that both at discharge and at 9 months after discharge HF patients reported problems and sexual concerns. However, this study did not report the development of new cases or recovered patients during this period of time⁹.

To gain more insight in sexual problems in HF patients, the following research questions were formulated to study in a large representative HF patient population:

1. Which demographic and clinical variables are related to difficulties in sexual activity?
2. Which QoL aspects are independently related to difficulties in sexual activity?
3. What is the course of difficulties in sexual activity over time?

Methods

Patient population

Data of patients participating in the COACH (Coordinating study evaluating Advising and Counselling in Heart failure) study were used. COACH is a multicenter, randomized clinical trial on the effect of education and counseling in HF^{14,15}. Between November 2002 and February 2005, 1023 patients from 17 Dutch hospitals were included in the COACH study. Patients were included in the study during admission for HF (NYHA functional class II

to IV), with HF as the primary diagnosis as confirmed by a cardiologist. During hospitalization patients were randomized to (1) basic support, (2) intensive support or (3) control treatment. Patients were 18 years or older and had evidence of structural underlying heart disease as shown at cardiovascular imaging. Reasons for exclusion were: concurrent inclusion in a study requiring additional visits to health care personnel; restrictions that made the patient unable to fill in data collection forms; invasive intervention within the last 6 months or planned during the following 3 months; or ongoing evaluation for heart transplantation. All patients gave written informed consent. Patients completed questionnaires and were interviewed by an independent interviewer not involved in care for these patients. All patients were treated from hospital discharge until 18 months afterwards hospital discharge.

The study was performed conform the principles outlined in the Declaration of Helsinki and was approved by the Committee for Ethics in Medical Investigations.

Data collection

Difficulties with sexual activity

Data on sexual activity in the COACH study were collected during index hospitalization and follow up. To minimize the confounding effect of the recent hospitalization on sexual activity, we used the data on sexual activity at 1 month after discharge. Sexual activity was assessed by the following question of the Minnesota Living with Heart Failure (MLwHF) questionnaire¹⁶: ‘Did your heart failure prevent you from living as you wanted during the past month by making your sexual activities difficult?’ Scoring format consists of 0 (no difficulties in sexual activity) and 1-5 (very little - very much difficulties). For the ‘course of difficulties in sexual activity’, data at 1 and 18 months after discharge were used. Four groups were created based on the scores at the two different time

points: continued difficulties (at 1 and 18 months difficulties with sexuality); new onset difficulties (no problems at 1 month and problems at 18 months); recovered difficulties (problems at 1 month but not at 18 months), and no difficulties (at 1 and 18 months). Data on sexual activity was also collected at 6 and 12 months after discharge. These data were analyzed as well, however results do not differ from the current results at 18 months after discharge. For reasons of readability, it was decided not to include these results.

Demographic and clinical characteristics

Data on demographic and clinical characteristics were collected from chart review, interviews and questionnaires. Depressive symptoms were measured with the Center for Epidemiological Studies Depression scale (CES-D), a 20-item self report questionnaire designed to measure depressive symptoms in the general population and has been widely used with the medical ill. A total sum score is used (0-60), with higher scores indicating more depressive symptoms^{17,18}.

Functional capacity was measured by the 6-minute walking test (6MWT) on a predefined course. Patients were instructed to walk as many meters as they could within 6 minutes. At standardized moments the instructor told the patients the amount of time remaining. Patients were allowed to stop or slow down if necessary. The 6MWT is a reliable and well validated test for functional capacity in HF patients¹⁹.

Quality of life

Data on QoL were collected using several questionnaires completed at 1 month after discharge. Disease specific QoL was measured with the MLwHF questionnaire¹⁶, a 21-item questionnaire assessing how HF has affected the life of the respondent during the last month. The questions cover symptoms and signs relevant to HF such as physical activity, social

interaction, sexual activity, work and emotions. Three scores can be determined: an overall score (21 items, 0-105), the physical dimension (8 items, 0-40) and the emotional dimension (5 items, 0-25). Higher scores mean worse QoL. The item on sexual functioning is in neither one of both dimensions, however it is part of the total score, therefore the total score was excluded from the analyses.

Overall well-being was assessed by Cantril's Ladder of life. This is a single-item measure which asks to rate the sense of well-being on a ladder, with 10 reflecting the best possible life imaginable and 0 reflecting the worst possible life imaginable. A higher score indicates better well-being²⁰.

General QoL was assessed by the Medical Outcome Study 36-item General Health Survey (RAND-36), a self-report questionnaire of general health status. It is a well-validated generic, 36-item questionnaire that includes 9 health concepts that represent dimensions of QoL: physical functioning, social functioning, role limitations because of physical functioning, role limitations because of emotional functioning, mental health, vitality, bodily pain, general health and perceived health change. Each dimension has a score between 0 and 100; a higher score means better QoL²¹.

Statistical analysis

Data are presented as mean \pm standard deviation or as percentages unless stated otherwise. Univariate analyses were carried out by using Mann-Whitney U for continuous or Chi² for categorical variables. Logistic regression analysis was performed to assess which demographic and clinical variables were independently associated with difficulties in sexual activity. Difficulties in sexual activity was used as the dependent variable. Based on univariate differences with $p < 0.10$, the following variables were inserted in the regression model, using backward methods: gender, age, living with a partner, left ventricular ejection

fraction (LVEF), CES-D, 6MWT, ACE/ARB, diuretics, Ladder of life, MLwHF physical and emotional dimensions, and the following dimensions of the RAND-36: social functioning, physical role limitations, emotional role limitations, mental health, vitality, bodily pain and general health. Student's t-tests were carried out to compare the change in the independently associated QoL scores (score at 18 months minus score at 1 month after discharge) and the number of hospital admissions between new onset patients and patients with no difficulties.

Analyses were performed using SPSS 16 (SPSS Inc., Chicago, USA). Outcomes were considered statistically significant when $p < 0.05$.

The COACH study was supported by a program grant from the Netherlands Heart Foundation (grant 2000Z003). Additional unrestricted grants for the main COACH study were obtained from Biosite Europe, France, Roche Diagnostics, The Netherlands and Novartis Pharma BV, The Netherlands. The authors are solely responsible for the design and conduct of this study, all study analyses, the drafting and editing of the paper and its final contents.

Results

Patients

Of the 1023 patients included in the COACH study, 44 died within 1 month after discharge. Of the survivors, 792 (81%) patients completed the question about sexuality of the MLwHF questionnaire at 1 month after discharge (mean age 69 ± 12 ; 35% female; mean LVEF $33\% \pm 14$). The 187 patients who did not complete this question were significantly more often female, older, living without a partner, in NYHA III-IV at discharge, diagnosed with diabetes, had a higher LVEF and walked less far on the 6MWT. Of the 187 patients who

survived the follow-up at 1 month after discharge, but specifically did not complete the question on sexual difficulty, 51 patients did fill out the rest of the MLwHF questionnaire.

At 18 months after discharge, 638 (81%) of the 792 patients were alive and 555 (87%) patients completed the question on sexual activity both at 1 and 18 months after discharge.

Difficulties with sexual activity

Of the 792 patients, 380 (48%) reported difficulties in sexual activity at one month after discharge. Almost half of these patients (n=186) reported considerable difficulties, they reported that HF prevented them *very much* of living as they wanted by making their sexual activities difficult.

HF patients who perceive sexual difficulties were more often male (76% vs. 54%, $p<0.001$), younger of age (66 vs. 72 years old, $p<0.001$) and more often living with a partner (82% vs. 49%, $p<0.001$), had a lower LVEF (32% vs. 35%, $p=0.007$), higher score on a depression scale (16 vs. 15, $p=0.035$) and walked further on the 6MWT (272m vs. 244m, $p=0.013$) (Table I). At hospital discharge more patients reporting sexual difficulties had a prescription of ACE/ ARB (88% vs. 83%, $p=0.019$). No differences were found regarding beta-blocker use and the assigned COACH intervention.

Patients with sexual difficulties had significant lower QoL compared to patients without sexual difficulties on both the physical and emotional dimensions of the MLwHF questionnaire (23 vs. 17 and 9 vs. 6, $p<0.001$, Table II). Six out of nine dimensions of the RAND-36 differed significantly between the patients with and without difficulties in sexual activity. Patients who perceive difficulties had significant lower QoL scores on social functioning, physical and emotional role limitations, mental health, vitality and general health.

In multivariate analyses, living with a partner (odds ratio (OR) 3.76, 95% confidence interval (CI) 2.58-5.48), younger age (OR 0.96, 95% CI 0.94-0.97), male gender (OR 3.08,

95% CI 2.10-4.43), overall wellbeing (OR 1.13, 95% CI 1.00-1.27), physical (OR 1.06, 95% CI 1.06-1.08) and emotional QoL (OR 1.07, 95% CI 1.03-1.10) were independently associated with difficulties in sexual activity due to HF that prevented patients from living as they wanted (Table III).

Course of difficulties in sexual activity

At 1 month after discharge, 270 of the 555 patients (49%) reported difficulties in sexual activity and at 18 months after discharge, 268 (48%) patients reported difficulties in sexual activity in some degree. Analyses over time show that of the 270 patients who reported sexual difficulties at 1 month after discharge, 80 patients (30%) recovered at 18 months follow up and 190 (70%) patients still reported difficulties. Of the 285 patients who did not report sexual difficulties at baseline, 207 (73%) did not report difficulties at 18 months as well, and 78 (27%) developed difficulties during 18 months follow up (new onset difficulties) (Figure 1). Compared to patients without difficulties, patients who developed sexual difficulties were more often male (55% vs. 78%, $p<0.001$) and living with a partner (44% vs. 74%, $p<0.001$). Furthermore patients who remained without difficulties, improved in QoL over time compared to new onset patients whose QoL scores did not change or worsened (change scores physical QoL -3.5 vs. 0.9, $p=0.001$, change scores emotional QoL: -2.2 vs. 0.04, $p=0.002$, changes scores wellbeing: 0.42 vs. -0.01, $p=0.047$). The number of hospital admissions did not differ between both groups (0.24 vs. 0.32, $p=0.376$).

Discussion

To our knowledge, this is the first study to explore the relationship between perceived difficulties in sexual activity due to HF and a considerable number of demographic variables, clinical variables and QoL aspects, and reports the course of difficulties in sexual activity, in a

representative HF patient population. Almost fifty percent of HF patients perceive difficulties in sexual activity due to their disease, and the majority (70%) of these patients continued to report difficulties after an 18 month recovery period. This was a remarkable difference with perceived difficulties experienced by 20-30% of healthy elderly²².

Male gender, younger age, and living with a partner were independently associated with perceived sexual difficulties. Patients who reported difficulties in sexual activity had significant lower disease specific QoL and overall well-being compared to patients who did not perceive sexual difficulties. We did not find an independent relation of difficulties in sexual activity to disease severity markers like NYHA, LVEF or BNP or beta blocker use. Also the use of tobacco or alcohol, having diabetes, and number of medications, as described in other studies were not found to be related to sexual activity^{9,12}, possibly due to an older and larger study population.

We believe that the present analysis is clinically relevant and extends previous studies by using a large group of older male and female HF patients. Previous studies assessing the relationship between patient characteristics and sexual functioning, used small and predominantly male patient groups^{9,12}.

Our study is also unique in the sense that we chose to include both patients with and without a partner. Of course we realize that having a partner is strongly associated with the perception of sexual problems, since patients who have a partner can be expected to be confronted more often with those problems as part as their daily life²³. However, our study also showed that 18% of the patients who perceived difficulties with sexual activity were living without a partner, thus not only patients with a partner experience sexual difficulties due to HF that prevent them from living as they want. It is important to report the prevalence in dysfunction in both patients with and without a partner, since patients might define sexual activity broader than having intercourse (e.g. masturbation) and single patients might worry

about their (future) sex life. The second strongest variable related to difficulties in sexual activity was male gender. Of the patients who perceived difficulties in sexual activity 76% was male. Endothelial dysfunction is prevalent in HF patients and one of the main common denominators for erectile dysfunction, but not in female sexuality^{8,24}. Therefore problems in sexuality can be assumed to affect the male sexual function more than female sexual function. Although previous research mainly focused on male sexuality and erectile dysfunction⁸, our study shows that 24% of the patients who perceive difficulties in sexual activity are women. Heart failure symptoms like dyspnea, fatigue and exercise intolerance can be assumed to affect sexuality in both male and female patients.

We rather uniquely report on the course of perceived difficulties with sexual activities. We found that at both time points about half of the patients reported difficulties with sexual activities due to symptoms of HF. However, we also demonstrated that 30% of the patients, who reported difficulties at 1 month after discharge, did not report difficulties in sexual activity at follow up. Possible reasons for the decrease in difficulties might be stabilization of HF, increased physical capacity during recovery or possible use of PDE5 inhibitors. However at the same time, we found that 27% of the patients without difficulties at 1 month after discharge did perceive sexual problems at 18 months follow-up and that in 70% of the patients with difficulties these difficulties remained. Patients who continue to be without difficulties improved in QoL over time, in contrast to new onset patients, whose QoL stayed the same or worsened. These findings emphasize that sexual concerns need to be discussed more than once during treatment and should become an integral part of HF management and patient education^{25,26}. It is known that, although the majority of healthcare providers feel a responsibility to discuss sexual concerns with their patients, many do not address these concerns in their daily practice^{27,28}.

Several limitations of this study should be considered. First, perceiving difficulties in sexual activity was based on a single question from a larger QoL questionnaire. This results in a global measurement of difficulties in sexual activity. However, our results are comparable to studies which used more extensive questionnaires on sexual functioning⁹. Second, the specific question on sexual activity concerns perceived difficulties with sexuality due to HF and that prevent them from living as they want. We do not know if these patients actually have sexual problems, we only know that their HF affects their sexuality. Sexuality activity could for example be affected by HF symptoms like fatigue or dyspnea, which is not stated as an actual sexual problem. Therefore we do not know if these patients actually have sexual problems, for example problems with erection, or that other factors, like HF symptoms, make their sexual activities difficult and prevent them from living as they want. When interpreting the results, it should also be taken into account that not necessary patients who are male, living with a partner and younger of age actually have more difficulties in sexuality. It can be expected that these characteristics are associated with a higher likelihood of reporting difficulties with sexual activities that prevent the person from living as he/she wants. Finally our findings show that difficulties in sexual activity are related to QoL. Our data do not provide insight in the cause and effect in this relationship. Patients with difficulties in sexual activity can be expected to have a lower QoL, due to these difficulties. However, one can also imagine that a worse QoL can influence sexual relations, due to functional impairment and emotional problems.

This study provides an important step towards understanding the occurrence of sexual problems in HF patients. Perceiving difficulties in sexual activity caused by HF and preventing patients from living as they wanted, affect many HF patients. Furthermore these difficulties continue over time and influence the QoL of these patients. Therefore it is of great importance to counsel HF patients repeatedly on sexual activity during their treatment.

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Figure 1. Flowchart of patients and course of perceived difficulties in sexual activity.

Table I. Characteristics of patients with and without difficulties in sexual activity

	No difficulties (n=412)	With difficulties (n=380)	P
	Percentage or Mean \pm SD		
<i>Demographics</i>			
Gender (female)	46	24	<.001
Age	72 \pm 11	66 \pm 12	<.001
Living with a partner	49	82	<.001
<i>Clinical characteristics</i>			
Support			
Care as usual	33%	33%	.819
Basic support	32%	34%	
Intensive support	36%	33%	
NYHA III-IV	46	48	.514
LVEF %	35 \pm 15	32 \pm 14	.007
Ischemic heart failure	39	42	.536
Myocardial infarction	41	42	.928
Hystory of atrium fibrillation	42	42	.919
Hypertension	44	40	.329
Diabetes	29	24	.100
COPD	25	26	.743
BNP (pg/mL) median (IQR)	400 (180-808)	427 (194-888)	.272
BMI	27 \pm 5	27 \pm 5	.244
Smoking	11	14	.339

Length of disease (years)	2.6 ± 4.5	2.4 ± 3.8	.131
CES-D (discharge)	15 ± 11	16 ± 11	.035
6 min walk test distance (m)	244 ± 137	272 ± 134	.013
<i>Medication</i>			
ACE/ARB (discharge)	83	88	.019
Betablockers (discharge)	66	71	.147
Diuretics (discharge)	94	97	.072

Abbreviations: NYHA: New York Heart Association, LVEF: Left Ventricular Ejection

Fraction, COPD: Chronic Obstructive Pulmonary Disease, BNP: B-type Natriuretic peptide,

IQR: Inter Quartile Range, BMI: Body Mass Index, CES-D: Center for Epidemiological

Studies Depression Scale, ACE: Angiotensin Converting Enzyme, ARB: Angiotensin

Receptor Blocker

Table II. Quality of life scores of patients with and without difficulties in sexual activity

	No difficulties (n=412)	With difficulties (n=380)	P
	Mean scores \pm SD		
Ladder of life	6.4 \pm 1.6	6.2 \pm 1.6	.068
Minnesota living with HF			
Physical dimension	17 \pm 11	23 \pm 11	<.001
Emotional dimension	6 \pm 6	9 \pm 6	<.001
RAND36-Physical functioning	44 \pm 28	41 \pm 26	.152
RAND36-Social functioning	61 \pm 30	52 \pm 29	<.001
RAND36-Role lim. Physical	26 \pm 37	15 \pm 30	<.001
RAND36-Role lim. Emotional	54 \pm 46	41 \pm 45	<.001
RAND36-Mental health	72 \pm 20	67 \pm 21	.002
RAND36-Vitality	51 \pm 23	44 \pm 22	<.001
RAND36-Bodily pain	75 \pm 28	72 \pm 29	.066
RAND36-General health	46 \pm 20	42 \pm 18	.008
RAND36-Health change	35 \pm 28	33 \pm 31	.173

Table III. Adjusted associations between patients with and without difficulties in sexual activity

Variables	B (SE)	95% CI for Odds Ratio			p
		Odds Ratio	Lower	Upper	
Age	-.04 (0.01)	.96	.94	.97	<.001
Gender (male)	1.13 (0.20)	3.08	2.10	4.43	<.001
Living with a partner	1.32 (0.19)	3.76	2.58	5.48	<.001
Minnesota living with heart failure- Physical dimension	-.06 (0.01)	1.06	1.04	1.08	<.001
Minnesota living with heart failure- Emotional dimension	-.06 (0.00)	1.07	1.03	1.10	<.001
Ladder of life	.12 (0.06)	1.13	1.00	1.27	.049