Original Research

Assessment of Quality of Life Using Three Activity Questionnaires in Heart Failure Patients After Monthly, Intermittent Administration of Levosimendan During a Six-Month Period

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Introduction: Quality of life (QOL) in heart failure patients is severely compromised by the symptoms of the disease. Acute administration of levosimendan improves patients' symptoms for intervals of 7-10 days. The aim of this study was to assess the QOL in heart failure patients, after monthly, intermittent administration of levosimendan for a 6-month period, using 3 activity questionnaires: Specific Activity Questionnaire (SAQ), Left Ventricular Dysfunction 36 (LVD 36), and Minnesota Living with Heart Failure Questionnaire (LIhFE).

Methods: We prospectively studied 20 patients, age 61.0 ± 15.7 years (mean ± SD) with heart failure (NYHA III and IV). Levosimendan was administered intravenously for 24 hours (dose 0.1 mg/kg/min), 1 day every month for a 6-month period. Patients were asked to answer the questions of the 3 activity questionnaires SAQ, LVD36 and LIhFE before and after the end of the 6-month period.

Results: For the LIhFE (the best score is 0 and the worst 105) before levosimendan the score was 35.4 ± 18.6 and after 6 months 22.2 ± 13.0 ($p<0.0001$). SAQ (worst score is 0 and the best is 9) before levosimendan was 4.2 ± 1.6 and after 6 months 4.7 ± 1.3 ($p<0.05$). For the LVD36 (more 'right' answers, more severe condition) before levosimendan values were 52.6 ± 26.2 and after 6 months 27.4 ± 17.3 ($p<0.0001$). Before levosimendan patients had a mean left ventricular ejection fraction (LVEF) 30.3 ± 6.9, while after 6 months the LVEF was 32.1 ± 7.4 ($p=0.01$).

Conclusions: Levosimendan treatment improved both objective echocardiographic measurements and the subjective QOL questionnaires. LIhFE and LVD36 show a significant improvement in QOL in heart failure patients after a 6-month period of monthly intermittent administration of levosimendan. The SAQ showed a very small improvement, because it describes more strenuous activity, a situation unusual for these patients, who are severely symptom limited.

Heart failure is a serious, chronic condition whose prevalence (0.2-0.4% in the general population and up to 17% in people over 70 years of age) [1,2] continues to increase.[3] Its incidence is calculated to be around 0.2-0.3% per year.[4] It is associated with a poor prognosis and clinical instability, resulting in a high frequency of hospitalisations, decreased quality of life and considerable health care costs.[4]

In fact, heart failure is one of the chronic diseases that mainly affect quality of life.[5] The physical condition of patients is compromised by dyspnoea, fatigue and loss of muscular mass, and commonly by symptoms of the underlying cause of their condition (e.g. angina).[3] Also, dietary restrictions, difficulties in executing occupational and family responsibilities, progressive loss of self-reliance and self-control, the side ef-

fects of medication and recurrent hospitalisations are also taken into account, and it is easy to understand how the quality of life of these patients can deteriorate.[3] For all these reasons, most of the studies of patients with heart failure take quality of life into account.

Moreover, quality of life is a good predictor of mortality and the need for hospitalisation.[6-9] It is also of great value in decision making as regards further procedures.[3] Usually, the instruments which are used to assess quality of life in heart failure patients are specially designed questionnaires.

The aim of this study was to assess the quality of life in heart failure patients, after monthly, intermittent administration of levosimendan for a 6-month period, using 3 activity questionnaires: Specific Activity Questionnaire (SAQ),[10] Left Ventricular Dysfunction 36 (LVD 36),[11] and the Minnesota Living with Heart Failure Questionnaire (LIhFE).[12]

Methods

We prospectively studied 20 patients (18 men, 2 women) with signs and symptoms of heart failure, whose age was 61 ± 15.7 years (mean ± SD), range 18-80. All had symptomatic heart failure and low left ventricular ejection fraction, due to coronary artery disease, dilated cardiomyopathy and postoperative tetralogy of Fallot (Table 1).

The 3 questionnaires were prospectively recorded and compared.

The levosimendan was administered in an intravenous dose once every month for a 6-month period.

Table 1. Characteristics of 20 patients with heart failure (values are percentages unless otherwise stated).

Age, years (mean ± SD)	61±15.7
Men	90
Aetiology of HF:	
Ischemic heart disease	80
Dilated cardiomyopathy	15
Fallot	5
NYHA class:	
III	40
IV	60
LVEF (mean ± SD)	30.3±6.9
Medication:	
b-Blocker	100
ACE-I	95
Diuretic	90

ACE-I – Angiotensin converting enzyme inhibitor; Fallot – postoperative tetralogy of Fallot; HF – Heart failure; LVEF – left ventricular ejection fraction; NYHA – New York Heart Association; SD – standard deviation.

The intravenous dose (0.1 mg/kg/min) was administered continuously over 24 hours. Every month patients stayed for 1 day in the hospital. All patients underwent an echocardiographic examination before levosimendan and 6 months after.

The SPSS software package was used for the statistical analysis. Values are given as mean ± standard deviation.

Questionnaires

The Specific Activity Questionnaire (SAQ)[10] is composed of 13 questions based on everyday activities and describes more strenuous activity for heart failure patients. Each activity corresponds to metabolic equivalents (METs, 1 MET=3.5 mlO_2/kg/min) predicted for a given type of activity. To each question the patient must answer "yes" or "no". The total score a patient achieves corresponds to the serial number of the last question to which an affirmative answer is given. The criterion for the affirmative answer is a patient's capacity to perform this specific activity without any symptoms (Table 2).

The Left Ventricular Dysfunction 36 (LVD 36)[11] questionnaire is composed of 36 questions. The patient is expected to answer each question with "true" or "false". The total score is derived by converting the number of the "true" answers' to a percentage of the total. The worst score is 100% and the best is 0% (Table 3).

The Minnesota Living with Heart Failure Questionnaire (LIhFE)[12] is composed of 21 questions. The patient is expected to grade each question from 0 to 5. His judgement must be based on how much his heart condition influenced the specific activity over the last month. The best score is 0 and the worst 105 (Table 4).

The 3 questionnaires, having been translated into Greek,[12] were completed under the supervision of the cardiac liaison nurse, who directed the questions. The order in which they were administered to the patients was randomised. All the patients completed the 3 questionnaires SAQ, LVD36, LIhFE before and after the end of the 6-month period.

Results

After the end of the 6-month period the patients showed improvement in all cardiac-specific questionnaires and in left ventricular ejection fraction. The 3 questionnaires also showed a significant improvement in the

Table 2. The Specific Activity Questionnaire (SAQ).

Can you complete the following activities without symptoms?	METs
1. Dress without stopping because of symptoms?	2.00
2. Do moderate work around the house like vacuum, sweep floors, or carry groceries?	2.50
3. Walk down a flight of stairs unassisted and without stopping?	3.00
4. Do heavy work around the house like strip and make the beds, hang out washing, or wash the car?	3.25
5. Do moderate gardening like weed or rake the leaves?	4.25
6. Push an electric or petrol mower on level ground?	4.50
7. Participate in moderate activities like walk at a normal pace (4 km/h) or play golf and carry the clubs?	4.75
8. Walk briskly around an oval?	5.00
9. Do outdoor work like split wood or dig in the garden?	5.50
10. Carry an 8-kg weight (e.g. load of wet washing) up 8 steps?	6.00
11. Carry at least 10 kg (e.g. a suitcase) up 8 steps?	7.00
12. Carry objects that weigh at least 35 kg (e.g. 11-year-old child)?	7.50
13. Participate in vigorous activities like swimming (crawl), jogging (8 km/h), cycling (17 km/h), singles tennis?	9.00

METs – metabolic equivalents.

quality of life in heart failure patients after a 6-month period of monthly, intermittent administration of levosimendan.

For the first questionnaire, SAQ, before levosimendan the score was 4.2 ± 1.6% and after 6 months 4.7 ± 1.3% ($p<0.05$). For the second questionnaire, LVD36, before levosimendan values were 52.6 ± 26.2 and after 6 months 27.4 ± 17.3 ($p<0.0001$). For the third questionnaire, LIhFE, before levosimendan the mean score was 35.4 ± 18.6 and after 6 months 22.2 ± 13.0 ($p<0.0001$).

Before levosimendan the patients had a mean left ventricular ejection fraction (LVEF) 30.3 ± 6.9%, while after 6 months the mean LVEF was 32.1 ± 7.4 ($p=0.01$).

Discussion

Chronic heart failure is a serious syndrome that affects the functional status of those patients who suffer from it. It also seriously limits their activities and influences their everyday living. The degree of activity curtailment depends on the stage of their heart failure; it may concern activities with very intense physical labour but also activities with considerably lighter intensity. The difficulties in their everyday living can affect their quality of life and as a result heart failure patients are self restricted, reducing any physical activity they might have had. They also experience a decrease of their muscular mass that further impacts their functional capacity. In addition they isolate themselves socially and lose their interest in life. Depression is well known to have an adverse effect on prognosis.

The assessment of the quality of life of patients with heart failure is important in the evaluation of their functional situation and the stages of the disease, and in making a decision about appropriate pharmaceutical and non-pharmaceutical treatment. The questionnaires for quality of life measurement are a valid means of assessment. There is a variety of questionnaires for patients with heart failure, most of whom show poor quality of life. This study is similar to one that was undertaken in the General Hospital of Agios Nikolaos, Crete, and measured the quality of life in patients with coronary heart disease and heart failure. In that study 2 different questionnaires were used, the SF-36 and EQ-5D, and the analysis indicated that the quality of life of coronary disease patients is quite low and even lower for heart failure patients.[13] From our results it appears that the 2 questionnaires LIhFE and LVD 36 show a significant improvement of the quality of life of patients with heart failure following the intravenous administration of levosimendan, while the SAQ questionnaire showed less improvement, probably because it describes more strenuous activity, which is unusual in patients with significant restriction of activity.

The results from the questionnaires parallel the results of the echocardiography studies, supporting the therapeutic action of levosimendan. Our findings are in agreement with the results observed in the study of Malliotakis et al, which showed that levosimendan may be a beneficial drug in low output states after cardiopulmonary bypass.[14]

Of course, the small number of patients that participated in this study limits the reliability of the results. Also, we used only the ejection fraction and questionnaires to access the quality of life of patients with heart failure. It would have been better if we had

Table 3. The left ventricular dysfunction questionnaire (LVD 36)

Please answer the following questions as you are feeling **these days**. *Tick either true or false for each question*.

Because of my heart condition:	**True**	**False**
I suffer with tired legs	☐	☐
I suffer with nausea (feeling sick)	☐	☐
I suffer with swollen legs	☐	☐
Because of my heart condition:	**True**	**False**
I am afraid that if I go out I will be short of breath	☐	☐
I am frightened to do too much in case I become short of breath	☐	☐
I get out of breath with the least physical exercise	☐	☐
I am frightened to push myself too far	☐	☐
I take a long time to get washed or dressed	☐	☐
If you do not do these activities for any reason other than your heart condition, then please tick false		
Because of my heart condition:	**True**	**False**
I have difficulty running, such as for a bus	☐	☐
I have difficulty either jogging, exercising or dancing	☐	☐
I have difficulty playing with children/grandchildren	☐	☐
I have difficulty either mowing the lawn or hoovering/vacuum cleaning	☐	☐
Because of my heart condition:	**True**	**False**
I feel exhausted	☐	☐
I feel low in energy	☐	☐
I feel sleepy or drowsy	☐	☐
I need to rest more	☐	☐
I feel that everything is an effort	☐	☐
My muscles feel weak	☐	☐
I get cold easily	☐	☐
I wake up frequently during the night	☐	☐
I have become frail or an invalid	☐	☐
Because of my heart condition:	**True**	**False**
I feel frustrated	☐	☐
I feel nervous	☐	☐
I feel irritable	☐	☐
I feel restless	☐	☐
I feel out of control of my life	☐	☐
I feel that I can not enjoy a full life	☐	☐
I've lost confidence in myself	☐	☐
Because of my heart condition:	**True**	**False**
I have difficulty having a regular social life	☐	☐
There are places I would like to go to but can't	☐	☐
I worry that going on holiday could make my heart condition worse	☐	☐
I have had to alter my lifestyle	☐	☐
I am restricted in fulfilling my family duties	☐	☐
I feel dependent on others	☐	☐
	True	**False**
I find it a real nuisance having to take tablets for my heart condition	☐	☐
My heart condition stops me doing things that I would like to do	☐	☐

also compared other factors, such as N-terminal pro-brain natriuretic peptide (NT-pro-BNP) and anaemia. In the study of Kallistratos et al, their results suggest that NT-pro-BNP plasma levels increase with increasing severity of heart failure.[15] Furthermore, Kremastinos emphasised the beneficial effects of erythropoietin combined with oral or intravenous iron, which provide additional opportunities to improve the quality of life and prognosis in anaemic heart failure patients.[16]

Table 4. The Minnesota Living with Heart Failure® questionnaire.

The following questions ask how much your heart failure (heart condition) affected your life during the past month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.

	Did your heart failure prevent you from living as you wanted during the last month (4 weeks) by -	**No**					**Very much**
			Very little				
1.	causing swelling in your ankles or legs?	0	1	2	3	4	5
2.	making you sit or lie down to rest during the day?	0	1	2	3	4	5
3.	making your walking about or climbing stairs difficult?	0	1	2	3	4	5
4.	making your working around the house or yard difficult?	0	1	2	3	4	5
5.	making your going places away from home difficult?	0	1	2	3	4	5
6.	making your sleeping well at night difficult?	0	1	2	3	4	5
7.	making your relating to or doing things with your friends or family difficult?	0	1	2	3	4	5
8.	making your working to earn a living difficult?	0	1	2	3	4	5
9.	making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
10.	making your sexual activities difficult?	0	1	2	3	4	5
11.	making you eat less of the foods you like?	0	1	2	3	4	5
12.	making you short of breath?	0	1	2	3	4	5
13.	making you tired, fatigued, or low on energy?	0	1	2	3	4	5
14.	making you stay in a hospital?	0	1	2	3	4	5
15.	costing you money for medical care?	0	1	2	3	4	5
16.	giving you side effects from treatments?	0	1	2	3	4	5
17.	making you feel you are a burden to your family or friends?	0	1	2	3	4	5
18.	making you feel a loss of self-control in your life?	0	1	2	3	4	5
19.	making you worry?	0	1	2	3	4	5
20.	making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
21.	making you feel depressed?	0	1	2	3	4	5

However, this study was already planned and carried out. The measurement of quality of life is not always objective, resulting in patients' over- or underestimation of their activities. Specifically, many times they answer negatively or positively to a question that might concern an activity, while in fact they never try to perform it because of their fear of possible physical fatigue. This is why the determination of the most suitable and more objective questionnaire would offer better assessment of the quality of life of heart failure patients.

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