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## Preliminary report on left-ventricular assist devices: are patients' and caregivers' psychosocial needs adequately addressed?

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**ABSTRACT.** Objectives. Patients implanted with a Left Ventricular Assist Device (LVAD) constitute a new population of chronic heart failure (HF) patients requiring continuous medical support and representing heavy costs – both direct and indirect – for the healthcare system. If there is consensus about the increased survival, the psychosocial outcomes, in terms of psychological wellbeing, behavioral and social functioning of both patients and caregivers, are still unclear. Overall, it is not clear if local health and social services are equipped to support them in their needs. We conducted an observational study on the psychosocial characteristics and needs of LVAD patients. Methods: Twenty-seven patients admitted for rehabilitation after implantation, and their caregivers were recruited. On admission, patients and caregivers were administered questionnaires assessing anxiety, depression, quality of life, level of social complexity and were interviewed about their social resources. At discharge, patients were re-assessed by questionnaires and patients/caregivers received a follow-up phone-interview after 8-12 months. Results. LVAD patients' emotional well-being and subjective quality of life improved during the rehabilitation stay and they confirmed their satisfaction with LVAD at follow-up. Problems emerged concerning the inadequate health and social assistance that LVAD patients receive once home. More than 50% of patients showed substantial social complexity, the burden of which fell on the caregivers, whose strain hardly declined over time, remaining at a level requiring psychological attention. Conclusions. Technological advances that improve LVAD patients' survival should be rapidly followed by adequate interventions by policy makers to improve also the local health/social assistance provided and to address patients and caregivers psychosocial needs over time.

**Key words:** LVAD, caregivers, psychosocial needs.

**RIASSUNTO.** REPORT PRELIMINARE SUI DISPOSITIVI DI ASSISTENZA VENTRICOLARE SINISTRA: LE RISPOSTE AI BISOGNI PSICOSOCIALI DI PAZIENTI E CAREGIVERS SONO ADEGUATE?

**Obiettivi.** I pazienti impiantati con un dispositivo di assistenza ventricolare sinistra (LVAD) costituiscono una nuova popolazione di pazienti con scompenso cronico, che richiede continuo supporto medico e rappresenta un costo importante per il sistema sanitario. A fronte di un generale consenso sull'aumento della sopravvivenza, i risultati in termini di benessere psicologico e psicosociale di pazienti e loro caregivers (cioè le persone loro legate affettivamente e che più se ne occupano) sono ancora poco chiari. In particolare, non è chiaro se i servizi territoriali siano pronti a supportare le loro necessità. Abbiamo quindi condotto uno studio preliminare osservazionale sulle caratteristiche psicosociali e sulle necessità di questi pazienti.

### Introduction

In recent years, patients with end-stage heart failure (HF) are increasingly being offered an implantable left-ventricular assist device (LVAD) to improve their prospects of survival (1). According to the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS), the current 2-year survival rate after LVAD implant is 70% (2). Thanks to the continuing technological advances in these devices, the surgical procedure is now less invasive and patients are usually in good physical condition early after the implantation and may gain a potentially good quality of life (QoL) after a specific rehabilitation period (3). Despite this positive evidence, LVAD patients constitute a new population of chronic HF patients, (4) potentially prone to developing neurological complications (5), who need constant follow-up and medical support, not only in relation to the LVAD (6). Some authors have recently demonstrated that the direct and indirect costs represented by these patients and their caregivers are very high and that the gain in terms of cost-effectiveness is questionable (7, 8). In particular, the psychosocial outcomes (i.e. psychological, behavioral and social functioning, together with subjective QoL) (9) both for patients and their caregivers seem a source of concern: in fact, while there is consensus about patient survival as the main visible and positive outcome, it is unclear how positive the complexity of the psychosocial factors associated to it are. To help clarify this issue, we are conducting an ongoing observational investigation of the psychosocial characteristics and needs of LVAD patients and their caregivers. We here present the preliminary findings in a group of LVAD patients and their caregivers, followed-up for 8-12 months after the implantation.

### Methods

#### Patients

We consecutively recruited, between September 2014 and March 2015, LVAD patients (n=27) admitted for routine inpatient rehabilitation after the implantation surgery in our Institute, and their caregivers (n = 13). The rehabil-

**Metodi.** Sono stati reclutati ventisette pazienti ricoverati in Riabilitazione dopo impianto LVAD e il loro principale caregiver, valutati all'ingresso con questionari specifici per l'ansia, la depressione, la qualità di vita e il livello di complessità sociale. Sono state inoltre valutate le risorse sociali disponibili mediante colloquio. Alla dimissione i pazienti sono stati rivalutati con gli stessi questionari. Dopo 8-12 mesi paziente e caregiver sono stati intervistati telefonicamente.

**Risultati.** Il benessere emozionale e la soggettiva qualità di vita dei pazienti migliorava durante il ricovero in Riabilitazione. I pazienti hanno confermato la loro soddisfazione per il device al follow-up, ma sono emersi problemi sull'inadeguatezza dell'assistenza territoriale, sia in termini medici che sociali. Più del 50% dei pazienti presentava un'importante complessità sociale, il cui peso ricadeva sui caregivers. Questi presentavano un sovraccarico che, pur calando lievemente nel tempo, rimaneva a livelli degni di attenzione psicologica.

**Conclusioni.** I progressi tecnologici che migliorano la sopravvivenza dei pazienti con LVAD dovrebbero essere seguiti da adeguati interventi da parte delle politiche socio-sanitarie, in modo da migliorare le risposte da parte dei servizi territoriali.

**Parole chiave:** LVAD, caregivers, bisogni psicosociali.

itation consisted of a cardiac physical training program of at least 20 days duration; patients were also trained in self-management of the device and underwent psychological counseling once/twice a week, depending on their needs. For the purpose of this study, patients and caregivers were assessed with several psychological questionnaires and underwent a structured interview inquiring about their social resources, i.e. personal financial resources, possible national and/or territorial financial assistance, transport facilities to/from the clinic, and adequacy of dwelling and caregiver support. Following discharge, patients were followed-up at 8-12 months by phone interview. All participants gave their signed informed consent to participate in the investigation, and the study was approved by our Institute's Scientific and Ethic Advisory Board.

### Questionnaires

The following questionnaires were administered to LVAD patients at admission:

- Beck Anxiety Inventory (BAI), Italian version (10). This is a 21-item questionnaire focusing on somatic symptoms of anxiety. Respondents indicate how much they have been bothered by each symptom over the past week. Items are self-rated on a 4-point Likert scale, from 0 (not at all) to 3 (severely). A cut-off score  $\geq 13$  indicates the presence of anxiety.
- Beck Depression Inventory II (BDI-II), Italian version (11). This is a 21-item self-report instrument assessing the existence and severity, over the past two weeks, of symptoms of depression. Scoring is on a 4-point Likert scale, from 0 to 3. A cut-off score  $\geq 11$  for males and  $> 13$  for females indicates the presence of depression.
- Minnesota Living with Heart Failure Questionnaire (MLHFQ). This 21-item questionnaire examines the effects of heart failure and its treatments on the person's QoL over the past month. Scores range from

0 to 105. A score  $\leq 24$  on the MLHFQ is considered to represent a good QoL, 25-45 represents a moderate QoL, and  $> 45$  a poor QoL (12).

- EuroQoL-5D (EQ-5D), a standardized self-administered instrument measuring health outcome. It is widely used throughout the world in different languages, including Italian (13). It consists of two parts: in the first part, respondents are asked to rate their health status in terms of 5 dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) from 1 (no problems) to 3 (severe problems). In the second part, respondents evaluate their general health status on a visual analogue scale (VAS) from 0 (worst imaginable health status) to 100 (best imaginable health status).
- LVAD Self Perception (LVAD SP), an 8-item VAS designed ad hoc to evaluate patients' subjective perception of the information received before and after implantation and difficulties in self-management of the LVAD. There is an additional question included for patients who have received the LVAD as a bridge to transplant decision.
- Social Environment Evaluation Schedule (SEES) (14). This questionnaire consists of four areas of evaluation: financial resources, adequacy of dwelling, presence/absence of caregivers, national/local benefits/services available). The score ranges from 40 to 400, and indicates the level of social complexity as follows: 40-140 = low complexity (e.g. a person with little financial problems and with available relatives living nearby), 150-270 = medium complexity (e.g. a person who has stopped working, is living with a working caregiver who is not available for assistance during the day), 280-400 = high complexity (e.g. a person who has financial concerns, no caregiver available, maybe living far from the hospital). This schedule was designed by the Italian National Professional Association of Social Workers, to evaluate people who are frail. For our purpose, it was used by our social worker to inform the patients' local health and social services about their needs.

Caregivers were separately administered the Family Strain Questionnaire-Short Form (FSQ-SF) (15) a 30-item self-administered instrument designed to screen caregivers' severity of stress and consequent psychological risk. Score indications are as follows:  $\leq 6$  = absence of risk; 7-12 = caregiver should be advised to seek counseling if the perceived stress increases; 13-20 = caregiver should be strongly recommended to seek psychological evaluation and support;  $>20$  = caregiver should be urgently referred to a psychologist and/or psychiatrist.

At discharge, 19 patients were re-administered the BAI, BDI-II, and EQ-5D. Eight patients, who lived far from our hospital, were discharged during the weekend, when their family could come to pick them up. In these cases it was impossible to administer the questionnaires.

### Follow-up

The Psychology Unit followed-up the patients with a structured phone interview at 8 to 12 months after the dis-

charge. They were asked about their health condition, possible difficulties encountered in their daily life because of the LVAD, social limitations, limitations in social assistance and access to homecare facilities and national benefits. Their answers were coded on a VAS (0=no problem/difficulty - 10=great problems/difficulty) or as dichotomous (yes/no). Caregivers were re-administered the FSQ SF.

### Statistical analysis

Descriptive statistics were performed as regards the characteristics of the sample. Pearson's correlation between the baseline variables was performed. Repeated measures analysis was carried out to verify any significant change over time. Data were analyzed by the means of SPSS 21.0. A value of  $p < 0.05$  was considered as significant.

## Results

Patients ( $n = 27$ ) were all males but one, with a mean age of 63 (SD 5) years (range 51-72 years); most (70%) had a school-level education  $< 9$  years, were married (70%), and retired (78%) (Table I). The LVAD implantation was a destination therapy for 7 of them, a bridge to transplant for 9, and a bridge to decision for 11. Pa-

tients underwent the psychosocial assessment 37 (SD 22) days (range 15-113 days) after the implantation. At admission, 22% of patients were above the cut-off level for anxiety and 78% scored high depression (the mean depression score for the whole sample was 17.4 (SD 9.7)). Patients evaluated their QoL as very poor in the MLHFQ (mean score 60.8, SD 16; range 33-97) and quite low on the EQ-5D VAS (mean score 59.2, SD 21.2). The majority stated in LVAD SP that they were adequately informed about the device before the implantation, that they did not perceive any difficulty in managing it, and that they had no fear in living with it. SEES scores showed 41% of patients in the medium social complexity range and 11% in the high complexity range.

Caregivers ( $n = 13$ ) were all females, with a mean age of 60 (SD 7) years (range 45-68 years); all but one were married to the patient (the exception was a sister); 69% had a school level of education  $< 9$  years and none were employed. Caregivers' mean score on the FSQ SF was 18.4 (SD 4.8) evidencing the need for strong recommendation to seek psychological evaluation and support.

At discharge (28.5, SD 9, days after admission), patients scored significantly better on both anxiety ( $p = .002$ ) and depression ( $p = .006$ ) as well as on the EQ-5 VAS ( $p = .000$ ) (Table II). No significant correlation between baseline patients' and caregivers' demographic and emotional variables was found.

Follow-up data were obtained for all the patients ( $n=27$ ) and 11/13 caregivers; of the two caregivers who dropped out, one was due to a marriage separation, and the other refused to participate. In general, patients declared that they managed their LVAD sufficiently well (VAS: 6.5, SD 4) and most (85%) knew who to call or what to do in the case of difficulty. The family support was perceived as very satisfying (VAS: 8.9, SD 2.8) and the majority (93%) reported they had good social relationships. In contrast, the medical and nursing home care was described as not completely adequate. Seventeen (63%) patients had officially received disability/invalidity status, but without any financial support except in 2 cases. Examining possible difficulties with the driving license renewal, answers varied greatly depending on the patient's geographical area of residence and the regulations of the competent authority. Caregivers scored better at follow-up on the FSQ FS (15.5, SD 7.6,  $p = .05$ , i.e. borderline significance); however, their perceived psychophysical distress remained in the same cut-off area, between 13 and 20, still indicating, therefore, that caregivers should be strongly recommended to seek psychological evaluation and support.

**Table I. Demographic characteristics of patients and caregivers**

	Patients (n=27)	Caregivers (n=13)
<b>Sex</b>		
Male	26	0
Female	1	13
<b>Age (years) mean; SD; min-max</b>	63; 5; 51-72	60(7) (45-68)
<b>School education</b>		
<9 years	19	9
>9 years	8	4
<b>Marital status</b>		
Married	19	12
Not married	1	1
Divorced	4	
Widowed	3	
<b>Employment status</b>		
Working	4	9
Not working	2	0
Retired	21	4
<b>Relationship with the patient</b>		
Spouse		12
Other		1

**Table II. Results of psychological questionnaires at patients' rehabilitation admission and at discharge (n. 19)**

	Rehabilitation admission	Discharge	p-value
BAI (mean-SD)	8.6 - 7.9	5.4 - 6.0	$p = .002$
BDI (mean-SD)	17.0 - 10.3	12.2 - 9.0	$p = .006$
EQ5VAS (mean-SD)	58.3 - 21.2	75.5 - 15.2	$p = .000$

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## Discussion

LVAD patients appear to gain real benefit from the in-hospital rehabilitation setting in terms of their emotional well-being and perceived QoL, as evaluated by the BAI, BDI-II and EQ-5D. The difficulties evident at admission in these areas do not seem to be related to the device, as patients stated that they received correct information, did not perceive any difficulty in managing it and denied possible fear of living with it. We then suppose that the distress and physical weakness which characterize the early post-implantation period may account for the picture of anxiety and depression and low perceived QoL observed at admission. This is confirmed by the improvement in patients' scores at the time of their discharge. Patients confirmed their satisfaction with the device at the follow-up investigation, declaring that they were in good health condition and that they were managing the device sufficiently well. In particular, they were satisfied with their family and social relationships, and these two conditions are without doubt fundamental in favoring the best coping possible (16,17). On the other hand, some problems emerged concerning the health and social assistance that an LVAD patient may count on once home. The nursing home care, when needed, seemed lacking or inadequately prepared; the modalities for driving license renewal by the competent authorities seemed unclear and not uniform for everybody; finally, no economic support was provided to people officially recognized as invalid by the national disability laws. These issues, that were evidenced by other Authors also, (18,19) may affect also caregivers' well-being: in fact, their strain was very little reduced over time and remained at a level which signaled the need for psychological attention. Caregivers, then, continue to feel anxiety and fear about the future, possibly finding themselves unprepared to manage the patients' daily needs and, overall, without specific support from the local health and social services. In fact, more than 50% of patients showed a medium-to-high level of social complexity, and the burden of this fatally falls back on the caregivers, despite the information passed on by the social worker to the local competent services.

Our study has some limitations. First, we were not able to administer the same questionnaires during the follow-up and consequently we lack a complete and comparable measure of anxiety, depression and QoL. Second, we were unable to offer psychological counseling to the caregivers, as they came to the hospital only during the week-end. For the same reason, we did not evaluate the caregivers at the discharge, as this was planned on the week-end in order to limit the distress and inconvenience for the families. So, we do not know exactly the trend of caregivers' strain over the course of the rehabilitation period. However, at the follow-up, all the caregivers interviewed stated that they felt alone in managing the situation, that they had too many tasks to perform, and that this was often due to the bureaucracy or of the lack of local resources.

These results lead us to conclude that advanced technology such as represented by LVAD implantation is not

matched by a similarly advanced local and national support system in terms of local health assistance and socio-economic support. This is not limited to the case of LVADs, and it is also not limited to Italy as a similar gap has been reported for other European countries, where regional disparities in the availability and quality of programs for managing chronic illness persist, as well as disparities in financial assistance policies (20,21). Some important incongruities need to be resolved as far as is possible, e.g. standardization of norms for driving license renewal; a review of national financial contributions needs to be undertaken, changing the criteria of access, and without overlooking the direct and indirect costs of caregiving (22).

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## Conclusions

The psychosocial needs of LVAD patients seem to be adequately addressed in the in-hospital rehabilitation setting, in particular as concerns their emotional wellbeing, perceived quality of life and self-confidence in managing the device, that remain stable over time. The same is not possible for caregivers, probably in part because they often cannot be treated in a psychological sense as they return home. After the discharge, however, even if the patients confirm subjective satisfaction about their health condition, the support provided by local health and social services seems scarce. This may cause distress for caregivers, who feel over-burdened with tasks and worries. Further studies are needed to better identify the flaws in the local health and social services and possible interventions to implement in order to address adequately LVAD patients' and their caregivers' psychosocial needs over time.

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