

Postoperative outcomes following rehabilitation in patients with left ventricular assist devices

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Abstract

Postoperative rehabilitation is a cornerstone of the recovery pathway following left ventricular assist device implantation (LVAD), and patients are expected to conduct an autonomous life thanks to improved technology and increased knowledge of

mechanical circulatory support. The primary purpose of the present study was to quantify clinical changes related to rehabilitation, in patients with LVAD: functional capacity, disability, and quality of life were identified as reliable outcomes to detect such changes.

The current study was a scoping review conducted searching three primary databases, namely PubMed, Scopus, and Cochrane Library, from their inception until January 2020.

After the selection process was completed, 12 citations were included in the present study. Three hundred eight three patients were included in the current analysis. Functional capacity, disability, and quality of life were investigated in 157, 215, 18 patients, respectively. Significant differences were found before and after rehabilitation. The mean walked distance at 6-Minute Walk Test improved from 319±96 to 412.8±86.2 metres ($p<0.001$), the mean score of the Functional Independence Measure from 68.4±11.8 to 92.5±10.8 points ($p<0.001$), the mean score of the Short Form-36 physical component from 32.7±29.9 to 55.5±24.7 points ($p=0.009$) and the mental component from 55.8±19.8 to 75.4±21.4 points ($p=0.002$). Postoperative rehabilitation is effective at improving functional capacity, disability, and quality of life in patients with left ventricular assist device; all these three domains are particularly expressive of the entity of patients' functional recovery.

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Introduction

The surgical treatment options for adults living with heart failure are increasingly becoming more common – due to the rising percentage of patients refractory to medical management – improving survival rates in those subjects who are not candidates for heart transplantation [1]. Left ventricular assist device (LVAD) implantation has four primary indications, i) bridge to transplantation, ii) destination therapy (lifelong support), iii) bridge to myocardial recovery, iv) bridge to candidacy (temporary support) [2]. Postoperative rehabilitation is a cornerstone of the pathway of care contributing to improving functional capacity and reducing readmission rates following implantation [3]. Patients with LVAD can return to their daily activities after surgery [4]. Typically, postoperative rehabilitation in patients with LVAD can be divided into several steps from the acute phase to hospital discharge [5]. The physiotherapeutic treatment takes place at every stage during the postoperative recovery commencing in the intensive care unit (ICU), as soon as the patient is awake [6]. In the early period immediately after implantation, the rehabilitative goals are mainly

directed to treat/prevent pulmonary complications; the ICU stay is characterised by the execution of respiratory exercises and in-bed positioning. Following ICU discharge, patients are usually subjected to motor recovery activities continuing respiratory therapy, as needed. In a more advanced phase of the postoperative timeframe, patients complete motor recovery and physical reconditioning, and starting self-administered exercise and becoming more socially active [5]. Significant complications of rehabilitative interest are primarily represented by stroke and respiratory failure [7]. Although several studies have been published discussing in detail rehabilitation in LVAD patients, to date, there is no available data defining cut-off values related to rehabilitative outcomes in such a population.

The primary purpose of the present study was to quantify clinical changes related to rehabilitation in patients with LVAD. To this end, the 6-Minute Walk Test (6MWT) for functional capacity, Functional Independence Measure (FIM) for disability, and the Short Form-36 (SF-36) for the quality of life were identified as reliable tools to detect such changes. The secondary aim of the study was to establish cut-off values for the variables investigated, considering the existing literature.

Materials and Methods

Study design

The current study was a scoping review [8] conducted by searching three primary databases, namely Cochrane Library, Scopus, and PubMed; the search went through the selected databases from their inception until January 2020. The search was done in the following fields; PubMed (all), Scopus (title, abstract, keywords), Cochrane Library (title, abstract, keywords).

Search strategy

Each database was searched using three Medical Subject Headings (MeSH) keywords; 1) LVAD, 2) physiotherapy and 3) rehabilitation. The MeSH terms were matched using the Boolean operator AND. After that, two search strings were built to search databases; “LVAD AND rehabilitation” and “LVAD AND physiotherapy”. Studies retrieved were evaluated by two independent reviewers who have compared and agreed on the results; the selection process was completed in February 2020.

Inclusion criteria

The present study included adult patients (>18 yrs) with no restrictions on gender, citations describing postoperative rehabilitation in LVAD patients with related outcome measures, and studies conducted in all settings (acute, sub-acute, long term care) with no restrictions regarding publication date. For the current research, the 6MWT, the FIM and the SF-36 were used to assess outcomes related to rehabilitation in the fields of functional capacity, disability, and quality of life, respectively.

Exclusion criteria

Paediatrics patients (<18 yrs) were not included as well as those citations such as abstracts; conference proceedings; editorials; case reports; letters to the editor; or written in languages other than English, Spanish, French, Italian; investigating outcome measures not related to the postoperative rehabilitation. Citations reporting measurements tools other than 6MWT, FIM, and SF-36 were also excluded from the present analysis. Blood samples and

chemistry tests on urine were not considered a measure of outcome for the present study as well as all types of imaging, biomarkers related to an organ function, survival rates, cardiopulmonary exercise test, spirometric analysis; length of hospital stay was not considered an outcome. Thus, all citations, as mentioned above, were not regarded as suitable for inclusion.

Data analysis

Each outcome measure was studied through meta-analytic methods and forest plot graphs. For each study, data have been expressed as mean and standard deviation. We used the standardised mean difference (SMD) for measurement of the effect (difference in means between before and after rehabilitation) [9]. For each outcome, a figure with graphs is presented: a forest plot combines the mean control values with 95% confidence intervals in every study (effect size). We explored heterogeneity across studies using the I-squared index. The meta-analyses were performed with both the Inverse Variance method (fixed effect) and the DerSimonian-Laird method (random effect); the Cochrane guidelines state that an I-squared value less than 40% would mean that the heterogeneity across studies might be not essential [10]. In forest plots, both fixed and random effect methods have been reported. All results are reported with 95% confidence intervals. A p-value <0.05 was considered to indicate statistical significance. Statistical analyses were performed using Stata version 12 SE (Stata Corp., College Station, TX, USA).

Results

The search returned a total of 321 citations, and after duplicates removal, 211 documents were assessed for eligibility. At the end of the selection process, 12 articles were retrieved for final analysis: nine were observational studies [3,11-19], while three were experimental trials [15,20,21]. A total of 383 patients (mostly males, as shown in Table 1) aged 59.2 ± 12.3 years were included in the final analysis (Figure 1); they were subjected to different types of rehabilitation with diverse intensity, frequency, and duration (Table 1).

Functional capacity using the 6MWT was investigated in 157 (41%) out of 383 patients, aged 54.6 ± 12.4 years, included from six studies; in that series, patients increased the mean walked distance after rehabilitation (Table 2).

Disability using the FIM was investigated in 215 (56%) out of 383 patients, aged 63.3 ± 10.6 years, gathered from five studies; the FIM score improved after rehabilitation was completed (Table 2).

Quality of life using the SF-36 was investigated in 18 (5%) patients out of 383, aged 46.7 ± 13.9 years, gathered from two studies; either the physical and the mental component scores were analysed (Table 2).

Significant differences before and after rehabilitation were detected for 6MWT, FIM, and SF-36 (Table 2); the outcomes in all the domains investigated in the current analysis improved postoperatively (Figures 2-4). As previously highlighted, SMD has been used to detect changes before and after rehabilitation (Figures 3 and 4); in this regard, an SMD of 0 means that rehabilitation has no effect on the investigated domains. SMD greater than 0 indicates the degree to which rehabilitation is effective [9].

Regarding the treatment modalities, they were heterogeneous and different timeframe have been adopted across the studies, as shown in Table 1. Furthermore, there was considerable heterogeneity regarding the initiation of treatment that commenced ranging

Table 1. Included studies (n=12).

Authors(year) [Ref.]	LVAD patients (n) {n of M}	Intervention	Measures	Main findings
Racca <i>et al.</i> (2018) [11]	(46){41 M}	Patients were enrolled in a rehabilitation programme (at least 3 weeks duration) 42±44 days after the operation. It comprised respiratory exercises, endurance training, walking or cycling, and limbs/trunk exercises.	6MWT	6MWD: was measured at the entry of the study and at discharge. The distance walked increased by 129±114 metres after rehabilitation.
Schmidt <i>et al.</i> (2018) [12]	(68){59 M}	Patients were enrolled in a rehabilitation programme (at least 3 weeks duration) 32±14.8 days after implantation. The programme included resistance exercise particularly focused on lower extremities using exercise machines or elastic bands. Endurance training was also executed on a bicycle ergometer.	6MWT	6MWD: was measured at the beginning and at the end of rehabilitation. The distance walked increased by 80.3±82.5 metres.
Marko <i>et al.</i> (2017) [16]	(10){-}	Aerobic (bicycle ergometer) and strength training (lower extremities) limiting the exercise exertion to somewhat hard in the Borg scale. The programme included also coordination and balance training, and walking.	6MWT	6MWD: was measured in 10 patients who completed a second rehabilitation programme. The distance walked increased by 59±7 metres after rehabilitation.
Yost <i>et al.</i> (2017) [3]	(90){75 M}	Three hours therapy daily including hand dexterity and grip strength. The programme also included transfers, gait training, and stairs. Patients were admitted to the rehabilitation programme after 32.1±20.7 days.	FIM	FIM: score improved by 28.4±12.3 points after inpatient rehabilitation.
Kerrigan <i>et al.</i> (2014) [15]	(16){-}	Supervised exercise 3 sessions per week for 6 weeks (18 sessions) including a 5-min warm-up, treadmill and stationary cycle or arm ergometer or recumbent stepper.	6MWT	6MWT: baseline (350.1±64.7 metres); follow-up (402.4±89.3 metres).
Alsara <i>et al.</i> (2014) [17]	(47){40 M}	Individual plan of care addressing impairments and activity limitations. The inpatient programme lasted 6.6±3.9 days.	FIM	FIM score improved significantly (77.1 vs 95.2 points).
Chu <i>et al.</i> (2014) [18]	(47){-}	Inpatient rehabilitation lasting 20.4±10.9 days.	FIM	FIM score: mean difference before/after 23.4 points.
English <i>et al.</i> (2013) [19]	(20){-}	Inpatient rehabilitation lasting 11.6±3.9 days.	FIM	FIM: mean score improved by 22.1 points.
Karapolat <i>et al.</i> (2013) [14]	(11){9 M}	Supervised CR consisting of 90-min sessions, 3 times a week, for 8 weeks (aerobic, flexibility, strengthening, breathing, and relaxation exercises).	SF-36	SF-36: significant improvements were registered after treatment in the following items: physical role, pain, vitality, emotional role, and mental health.
Nguyen <i>et al.</i> (2013) [13]	(11){8 M}	Standard inpatient rehabilitation: 3 h per day of comprehensive physical and occupational therapy. The mean duration was 17.5±8.9 days; patients were admitted to the programme 48.6±18.2 days after implantation.	FIM	FIM gain was 28.6±10.2 points after treatment inpatient rehabilitation.
Hayes <i>et al.</i> (2012) [21]	(7){6 M}	Walking maintaining an intensity of somewhat hard Borg scale. Exercise training: 1 h, 3 days weekly for 8 weeks. Training consisted of 15 minutes of stationary cycling and 15 minutes of treadmill. In addition, strength training was implemented by 3 upper limb and 3 lower limb exercises using weight machine (2 sets of 10 repetitions). Patients attended 21.3±1.5 exercises sessions.	SF-36 6MWT	SF-36: the total score improved significantly after treatment. 6MWT: was measured at the beginning and at the end of rehabilitation. The distance walked increased from 351±77 to 531±131 metres.
Laoutaris <i>et al.</i> (2011) [20]	(10){10 M}	Inpatient rehabilitation programme (10 weeks duration) including 30-45 minutes walking, respiratory exercises (IMT), early mobilisation, progressive aerobic and resistance training.	6MWT	6MWT: pre-training (462±88 metres), post-training (527±76 metres).

Ref., reference; LVAD, left ventricular assist device; M, males; 6MWT, 6-Minute Walk Test; 6MWD, 6-Minute Walk Distance; FIM, Functional Independence Measure; CR, cardiac rehabilitation; SF-36, Short Form-36; IMT, inspiratory muscle training.

from 1 to six months after surgery. Although in several included studies the point in time when rehabilitation began – after LVAD implantation – was specified as shown in Table 1 [3,11-13], in others, this variable was not available preventing us from providing more details.

Discussion

In the last decade, an increasing interest has been mounted on the effects and techniques of postoperative rehabilitation in LVAD patients. As a matter of fact, LVADs are increasingly used as destination therapy in patients with end-stage heart failure. With the current study, we found that 6MWT, FIM and SF-36 were the most

used evaluation tools to detect clinical changes related to rehabilitation in such a class of patients. Nevertheless, in conducting our research, we observed that other variables are attracting increasing interests among authors, such as pulmonary function tests [14,20] and strength tests (handgrip and quadriceps strength) [15,22,23]. It should be argued that such a new trend will be better developed in the future expanding boundaries of knowledge in these specific topics; however, we believe that the analysis of more inclusive outcomes – as carried out in the current study – represent today a starting point to pave the way for further investigation. We were able to define specific values for each of the outcomes we investigated and, for the first time in literature, we can have these data available to compare our results with daily clinical practice. Indeed, 6MWT, FIM and SF-36 are particularly expressive of the entity of patients' functional recovery, following LVAD implantation.

Table 2. Differences before and after rehabilitation, and cut-off values of each domain.

Domains	N of studies	N of patients	Variables		p
			Before rehabilitation (mean±SD)	After rehabilitation (mean±SD)	
Functional capacity (6MWT), (m)	6	157	319.0±96.0	412.8±86.2	<0.001*
Disability (FIM), (pts)	5	215	68.4±11.8	92.5±10.8	<0.001*
Quality of life (SF-36), (pts)	2	18	-	-	-
Physical component score	-	-	32.7±29.9	55.5±24.7	0.009*
Mental component score	-	-	55.8±19.8	75.4±21.4	0.002*

SD, standard deviation; 6MWT, 6-Minute Walk Test; m, metres; FIM, Functional Independence Measure; pts, points; SF-36, Short Form-36; *p<0.05 was considered to indicate statistical significance.

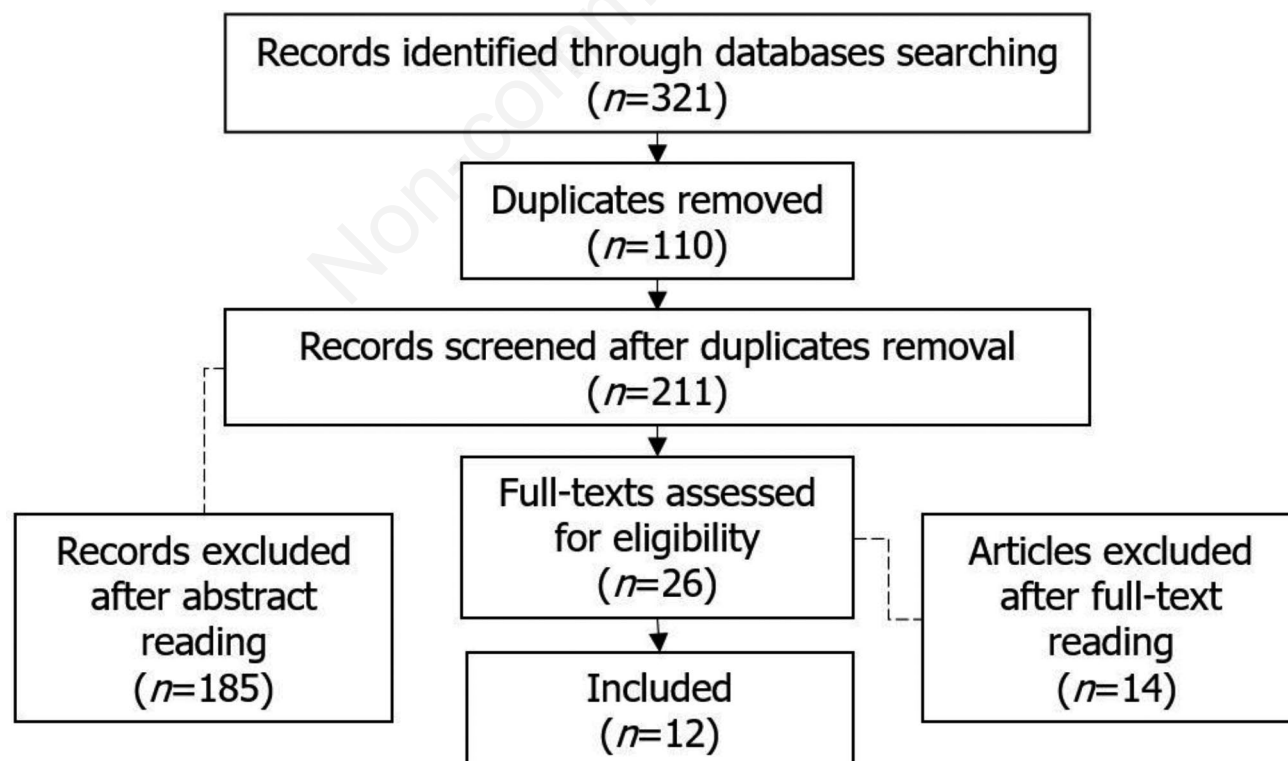


Figure 1. Search flow.

Outcome measures

Functional capacity can be defined as the person’s ability to perform activities that require physical exertion; the integrity of the cardiovascular, respiratory and skeletal muscle systems is

essential to determine individual functional capacity [24]. The 6MWT is a test to objectify functional exercise capacity; it evaluates the global responses of all body systems involved during exercise. The 6MWT is widely used for measuring the response to therapeutic interventions for pulmonary and cardiac diseases [25]. The

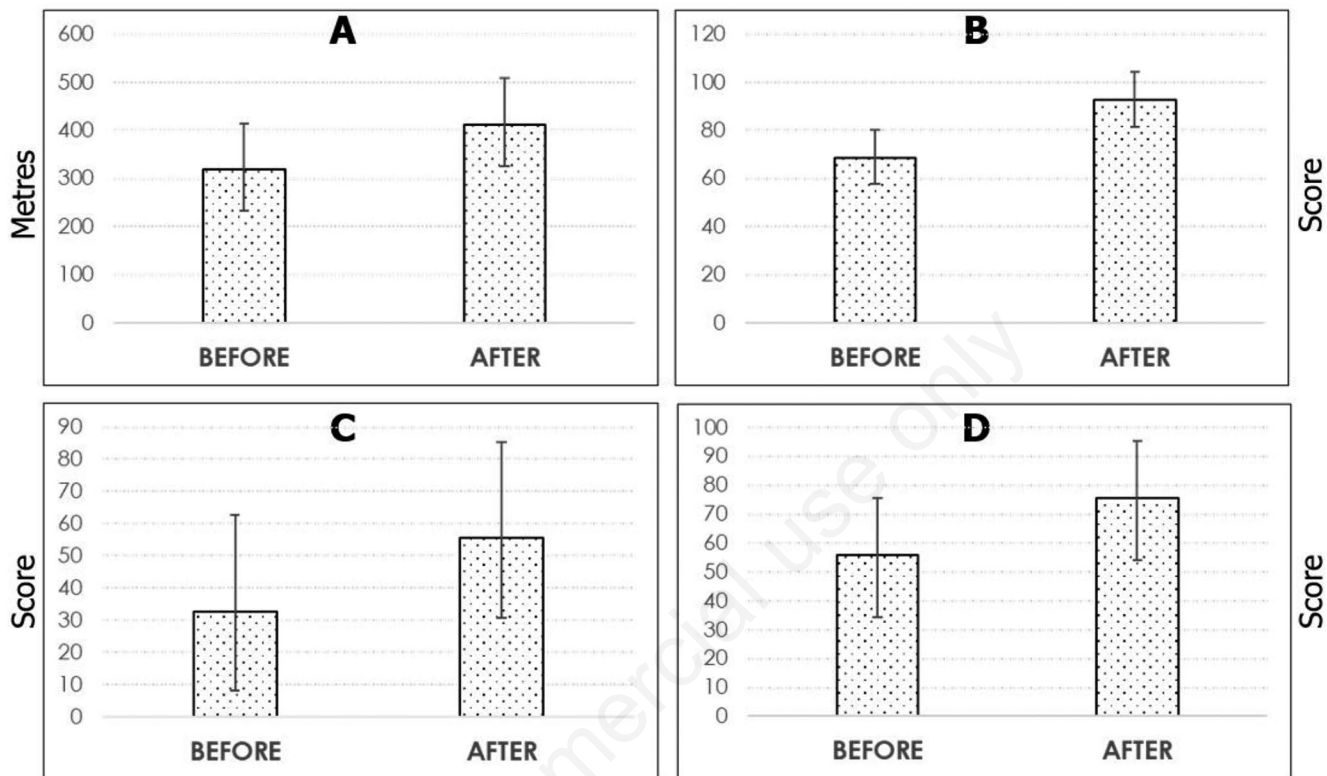


Figure 2. Differences before and after rehabilitation, in each domain. A) 6MWT test. B) FIM test. C) SF-36 physical component score. D) SF-36 mental component score. 6MWT, 6-Minute Walk Test; FIM, Functional Independence Measure; SF-36, Short Form-36.

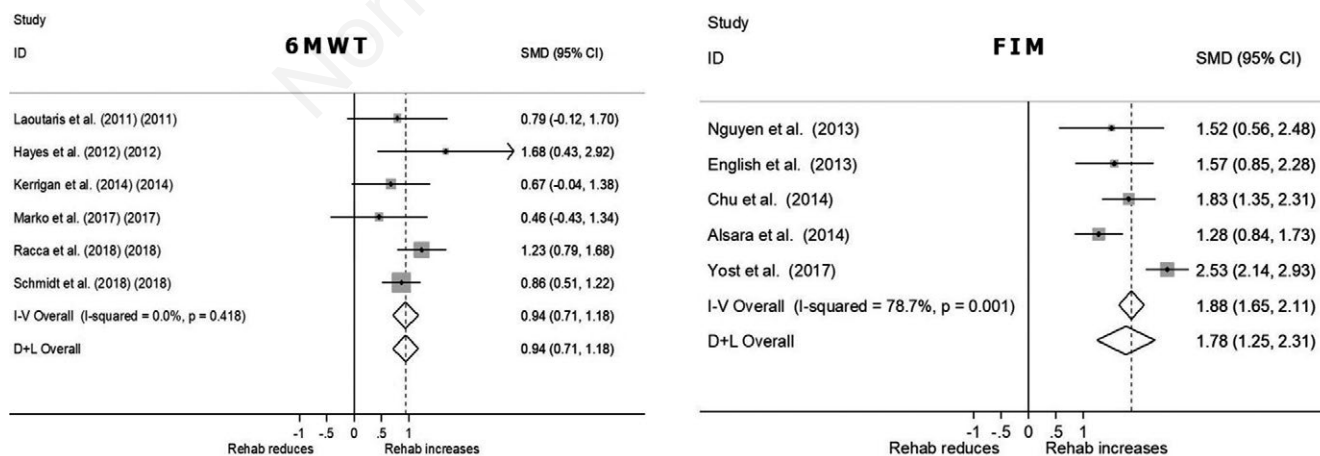


Figure 3. Forest plot of effect size estimates on rehabilitation: functional capacity (6MWT) and disability (FIM) domains. Squares represent the effect size estimate and horizontal lines represent the confidence intervals for each study. The diamonds represent the estimates of the overall effect size (in both fixed and random effects models). The vertical line represents the null hypothesis (SMD=0), whereas the vertical dotted line represents the overall mean difference from all studies. A positive effect size is identifying postoperative rehabilitation effectiveness. 6MWT, 6-Minute Walk Test; CI, confidence interval; SMD, standardised mean difference; FIM, Functional Independence Measure.

object of the test is to walk as far as possible for six minutes. Patients are permitted to slow down, to stop or to rest as necessary during its execution.

Disability is a complex phenomenon, reflecting the interaction between features of a person's body and features of the society in which he or she lives [26]. The FIM scale is used to determine the degree of disability that patients experience and the signs of progress that they make throughout rehabilitation [27]. FIM is comprised of 18 items grouped into two subscales; motor (13 items) and cognition (5 items). Each item is scored in a 7-point ordinal scale (min 1–max 7), the total score of the FIM ranges from 18 to 126; the higher the score, the more independent the patients is. The overall rating of the motor subscale ranges from 13 to 91 points while that of the cognition subscale ranges from 5 to 35 points.

Quality of life is an individual's perception of their position in living in the context of the culture and value systems in which they live and in relation with their goals, expectations, standards and concerns [28]. The SF-36 is a health questionnaire which includes one multi-item scale that assesses eight health concepts: 1) limitations in physical activities because of health problems; 2) limitations in social activities because of physical or emotional problems; 3) limitations in usual role activities because of physical health problems; 4) bodily pain; 5) general mental health; 6) limitations in usual role activities because of emotional problems; 7) vitality; and 8) general health perceptions [29]. The score of the SF-36 ranges from 0 to 100, with a higher rating indicating better health; low scores in the physical function scale are the expression of limitations in physical activities including bathing or dressing. In the same way, low scores on social functioning are typical in those patients who experience difficulties in regular social activities due to the physical and emotional health problems [30].

As we have previously highlighted, LAVDs are increasingly used as destination therapy due to the shortage of donors, reinforcing the need to detect clinical changes in a multifaceted clinical context rather than in some specific issues. However, the possibility to gather additional details regarding specific physical outcomes (*i.e.*, pulmonary function, body strength) can definitively contribute to planning a more efficacious and reliable postopera-

tive recovery pathway tailoring the rehabilitative intervention on singular patients' characteristics and needs.

Although the current analysis includes different types of outcomes, each contributed to identifying changes related to rehabilitation, postoperatively. In planning postoperative care for patients with LVAD, the results of our study can assist in optimising the physiotherapeutic intervention, definitively.

It should be noted that most of the studies had no control group. This was probably due to the fact each study aimed at detecting rehabilitation effects instead of the efficacy of a given rehabilitative treatment/modality over another. At the same time, we should not forget the population of LVAD patients is still representing a narrow context if we compare it with others rehabilitative cohorts (*e.g.*, chronic obstructive pulmonary disease, orthopaedic, musculoskeletal patients). In addition, it was not possible to gather further information regarding the presence of adults with congenital heart disease who should be considered paediatrics; nonetheless, lack of data about this variable would not alter the results of our analysis.

Limitations

The current study bears several limitations; firstly, it was not possible to identify a standardised rehabilitative treatment, as in each study the intervention was carried out with different modalities and commenced at different points of time, postoperatively. In this regard, from the available literature, it was not possible to precisely identify when patients started rehabilitation after implantation; high variability of this data did not allow to stratify the analysis considering this variable. Another limitation could be recognised in the absence of previously published cut-off values for the variables we investigated to compare our findings; at the same time, this represents the strength of our analysis that provides detailed data to be used for stratifying functional capacity, disability, and quality of life in such a patient population. Furthermore, when analysing figures regarding the SF-36, only 18 patients were included; on the other hand, this was the population available. In this regard, we guess this is not a limitation of the study; instead, more researches are needed in that field to enlarge such a specific cohort.

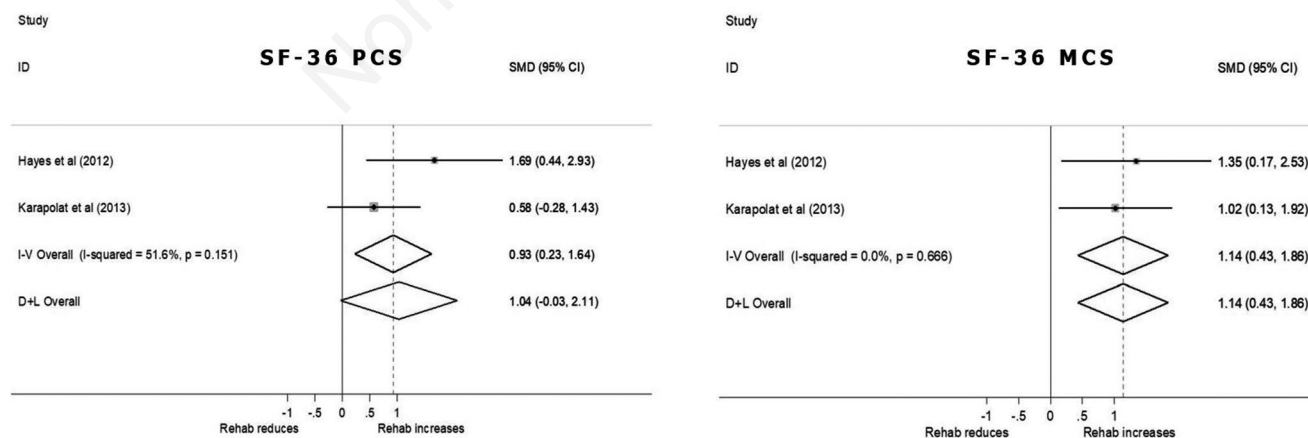


Figure 4. Forest plot of effect size estimates on rehabilitation: quality of life. Squares represent the effect size estimate and horizontal lines represent the confidence intervals for each study. The diamonds represent the estimates of the overall effect size (in both fixed and random effects models). The vertical line represents the null hypothesis (SMD=0), whereas the vertical dotted line represents the overall mean difference from all studies. A positive effect size is identifying postoperative rehabilitation effectiveness. SF-36 PCS, Short Form-36 Physical Component Score; CI, confidence interval; SMD, standardised mean difference; SF-36 MCS, Short Form-36 Mental Component Score.

Eventually, although we summarised in Table 1 the characteristics of the rehabilitative interventions, we did not provide a detailed description of the treatment. In this regard, we should not forget the present study is a scoping review conducted to identify critical characteristics of outcomes rather than physiotherapeutic procedures: so, we guess the analysis of the rehabilitative intervention can be worthy of a different and separate investigation. Nevertheless, a synthesis of the rehabilitative techniques has been provided in Table 1.

Conclusions

Postoperative rehabilitation is a cornerstone of the recovery pathway following LVAD implantation and patients are expected to conduct an autonomous life thanks to improved technology and increased knowledge of LVADs. Evidence indicates that rehabilitation has a positive effect on functional capacity, disability, and quality of life in patients with LVAD.

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