Exercise Guidelines for Inpatients Following Ventricular Assist Device Placement: A Systematic Review of the Literature

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ABSTRACT

Background: For patients with end-stage heart failure awaiting transplantation, lack of donor organs has created an increased need for alternatives such as left ventricular assist device (LVAD) implantation. The purpose of this study is to determine safe and effective exercise parameters for physical therapy in the acute care setting. **Methods:** A systematic literature review was conducted according to PRISMA guidelines using Sackett's Levels of Evidence to rate the evidence. Multiple databases were searched with inclusion criteria of: available in English, inpatient care up to 6 months postoperatively, description of intervention type and exercise parameters. Exclusion criteria: no defined exercise parameters, outpatient treatment, infection post VAD, or palliative or hospice care post VAD. **Results:** Six studies out of 1,291 articles met inclusion criteria. Common exercise parameters used were the Borg Rating of Perceived Exertion scale 11-13 (6-20 scale) or > 4 (0-10 scale), Dyspnea scale > 2 (0-4 scale) and > 5 (0-10 scale), mean arterial pressure (MAP) 70-95 mmHg, and LVAD flow > 3L/min. Levels of evidence ranged from case controlled to expert opinion. **Conclusion:** Current evidence on inpatient exercise parameters for patient's status post LVAD implantation is not sufficient to suggest definitive guidelines; however, these exercise parameters provide a reference for patient care.

Key Words: ventricular assist device, physical therapy, exercise

INTRODUCTION AND PURPOSE

An estimated 5.7 million Americans are affected by heart failure¹ with 550,000 new cases diagnosed annually and a survival rate of approximately 50%. This number accounts for an estimated \$10 to 40 billion annually in health care costs.² While heart transplantation is the recommended course of treatment for patients with end-stage heart failure,

fewer than 3,000 donor organs are available worldwide each year,^{2,3} creating an increased need for an alternative treatment such as ventricular assist devices (VADs). These mechanical circulatory assists are continuous or pulsatile flow pumps within the abdominal wall that bypass the malfunctioning ventricles to maintain optimal blood flow. Pulsatile flow pumps have an internal chamber with inflow and outflow valves that allow cyclical filling and emptying powered by either electrical or pneumatic systems.^{2,4} Continuous flow pumps are nonpulsatile and continuously draw blood from the left ventricle through the pump towards the ascending aorta.^{5,6} The use of VADs as bridge to transplantation has proven to be an excellent alternative with approximately 75% success rate lasting up to 3 to 4 years.⁷

The technological advances of VADs in recent years have increased health-related quality of life and exercise tolerance, improved end-organ dysfunction, normalized hemodynamics, and have allowed hospital discharge with a relatively low incidence of adverse events.^{2,8} Several studies have compared the outcomes associated with exercise capacity and quality of life for patients with VADs to patients with heart transplantation; immediately after implantation or transplantation with variable periods of outpatient follow-up.⁸ Effective rehabilitation programs have also been outlined for patients with a total heart transplant.⁸ Literature addressing exercise post VAD implantation has been reported to be limited by quality of evidence.⁸ To our knowledge, there are currently no systematic reviews reporting the safety and efficacy of exercise parameters for inpatients status post VAD placement. Given the technological advances and increased usage of VADs, it is important that physical therapists in the inpatient setting are knowledgeable of effective exercise guidelines in order to provide optimal management for these patients.

Thus, our purpose is to delineate safe and effective parameters for exercise in the inpatient setting for a patient status post VAD placement. Safe and effective parameters are defined as those that do not result in adverse consequences during exercise and produce favorable improvements recorded through the use of outcome measurements.

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METHODS

A systematic review of the literature was performed in the following databases: Scopus, EBSCO Cochrane Health Technology Assessment, EBSCO Cochrane Central Register of Controlled Trials, CINAHL, PubMed, and ISI Web of Science. Table 1 represents the search strategies performed for each database in agreement with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines for search and reporting processes. Our search included articles published since 1990 to include contemporary information and was open to all research designs in order for the search to be comprehensive.

Appropriate MESH terms were determined for each database and used respectively. The final search date was June 5, 2012. PRISMA provides a prospective 27 item

checklist and a 4-phase flow diagram including items essential for creating a systematic review.⁹ Results were limited to human studies that were published in English during or after 1990. Articles were further excluded if each contained exercise without defined parameters, outpatient treatment, focused on infection post VAD, or palliative or hospice care post VAD.

Articles were independently reviewed by two authors (RS and CB). All articles were originally reviewed by title. When a disagreement occurred between these two authors, further discussion was held to determine whether the article was to be included. In the situation that an agreement was not reached, a third author (JP) reviewed the article title to determine whether or not it was to be included. The same procedure was followed for review of abstracts (RS and CB) and then for full text inclusion (CH and DS). For articles in which abstracts were not available, two of the reviewers discussed whether or not the article would be included for full text review based on the article title. Refined inclusion criteria for the studies selected included acute inpatient setting up to 6 months postoperatively, patient's status post-VAD implantation of any age, as well as those articles which included exercise limitations and outcomes outlined in Table 2.

Kappa values were calculated to determine the interrater reliability between the investigators.¹² The articles were rated based on Sackett's Level of Evidence from the strongest (1) to weakest (5) levels (Table 3). All reviewers rated each article independently and came to a consensus on the proper level of evidence to assign.

The effectiveness of the exercise parameters were documented by common outcome assessment tools for cardiac patients such as peak oxygen consumption (peak VO₂), Functional Independence Measure (FIM), blood pressure response, and exercise tolerance.

RESULTS

The initial search resulted in 1,359 articles. Once duplicates were removed, 1,291 articles were included. Following the title review, the potential number of articles

Table 1. Search Strategies

<p>PubMed ((((VAD OR LVAD OR RVAD)) OR (right assist*)) OR (left assist*)) OR (ventricular assist*)) AND (((("Cardiovascular Diseases/rehabilitation"[Mesh]) OR "Cardiomyopathies/rehabilitation"[Mesh]) OR "Heart Failure/rehabilitation"[Mesh]) OR (((("Exercise"[Mesh]) OR "Exercise Test"[Mesh]) OR "Exercise Tolerance"[Mesh]))</p> <p>EBSCO CINAHL/EBSCO Cochrane Central Register of Controlled Trials/ISI Web of Science ("heart assist devices" OR "ventricular assist*" OR "VAD") AND ("exercise" OR "exercise tolerance" OR "exercise test") AND ("cardiovascular disease" OR "heart failure" OR "cardiomyopathies"))</p> <p>EBSCO Health Technology Assessments ("heart assist devices" OR "ventricular assist*" OR "VAD") AND ("exercise" OR "exercise tolerance" OR "exercise test"))</p> <p>Scopus ((ALL(REHAB*) OR ALL("PHYSICAL THERAPY")) AND (((ALL(CARDIOVASCULAR DISEASE) OR TITLE-ABS-KEY(HEART FAILURE) OR TITLE-ABS-KEY(CARDIOMYOPATHIES))) AND ((ALL(EXERCISE) OR TITLE-ABS-KEY(EXERCISE TOLERANCE) OR TITLE-ABS-KEY(EXERCISE TEST))) AND ((ALL(HEART ASSIST DEVICES) OR ((ALL(VENTRICULAR ASSIST*) OR TITLE-ABS-KEY(VAD))))))</p>

Table 2. Exercise Limitations and Outcomes Utilized in Search

Criteria for Safe Exercise*	Criteria for Effective Exercise*
<ul style="list-style-type: none"> Symptoms of exercise intolerance such as chest pain or palpitations ECG changes ST shifts > 1 mm Increasing ventricular arrhythmias Systolic blood pressure < 80mmHg or that which decreases by more than 20 mmHg Flow less than 3L/min Detection of reduced volumes Oxygen desaturation below 90% Acute neurological changes (eg, stroke or TIA) The device alarms Bleeding 	<ul style="list-style-type: none"> Minnesota Living with Heart Failure questionnaire^{10,11} Kansas City Cardiomyopathy questionnaires¹⁰ Health Related Quality of Life via SF-36⁸ FIM¹ Six-Minute Walk Test^{10,11} Improvements in exercise tolerance as demonstrated through increased VO₂ max, decreased MAP and exertional blood pressure, increased duration or intensity of exercise
<p>Abbreviations: ECG, electrocardiogram; TIA, transient ischemic attack; MAP, mean arterial pressure; FIM, Functional Independence Measure; VO₂ max, maximal oxygen consumption</p> <p>* Safe exercise did not result in these changes</p> <p>** Exercise parameters that result in improved outcomes as defined by outcome measures in use with patients post LVAD implantation</p>	

Table 3. Sackett's Level of Evidence

1A	Systematic Review of Randomized Controlled Trials (RCTs)
1B	RCTs with Narrow Confidence Interval
1C	All or None Case Series
2A	Systematic Review Cohort Studies
2B	Cohort Study/Low Quality RCT
2C	Outcomes Research
3A	Systematic Review of Case-Controlled Studies
3B	Case-controlled Study
4	Case Series, Poor Cohort Case Controlled
5	Expert Opinion

Adapted from Levels of Evidence.¹³ Oxford Centre for Evidence-based Medicine – Levels of Evidence (March 2009) Website. Available at www.cebm.net. Accessed June 4, 2012.

was narrowed to 129 (kappa=1.00; 95% CI 0.97 to 1.00). Abstract review further reduced the number to 40 (kappa=0.96; 95% CI 0.83 to 0.96). After reviewing the full text, 6 studies were included in this review after meeting all inclusion and exclusion criteria (kappa= 0.77; 95% CI 0.25 to 0.98). The entirety of the review process created a kappa agreement of 0.99 (95% CI 0.96 to 0.99) (See Figure 1).

All studies were retrospective and included a variety of study designs including two case series, two case controlled studies, one case study, and one expert opinion. All reviewed articles included patients with a left ventricular assist device (LVAD), 4 of which were pulsatile, and two centrifugal or continuous flow pumps. In rating the quality of evidence for the 6 articles, two were given a score of 3b, while 3 had a score of 4, and one a score of 5 (Table 4).

Effective Parameters and Outcomes

Table 4 provides a summary of articles in this review describing exercise parameters and therapeutic intervention that were provided, guidelines for terminating exercise, adverse effects resulting from therapy, and outcomes. Measures of improvement reported in the studies included peak VO_2 , metabolic equivalents (METs), FIM, blood pressure, oxygen saturation, heart rate, mean arterial pressure (MAP), respiratory exchange ratio, oxygen consumption at anaerobic threshold, and ventilatory response at peak exercise (VE/VCO_2). Below is a description of each exercise parameter with the associated outcomes.

Peak VO_2

Two studies examined peak VO_2 before and after exercise training in order to identify the effectiveness of the exercise program as illustrated in Table 4. De Jonge et al⁷ describe improvements of VO_2 increasing from 21.3 ± 3.8 ml/kg per min at 8 weeks to 24.2 ± 4.8 ml/kg per min at 12 weeks after implantation ($p < 0.003$; 95% CI 4.7 to 1.3). This study also describes the ventilation response to exercise that decreased from 39.4 ± 10.1 at 8 weeks to 36.3 ± 8.2 at 12 weeks after implantation ($p < 0.03$; 95% 0.4 to 5.8).⁷ Exercise parameters used to achieve these results were a Borg RPE scale of less than 4/10 or an exertional dyspnea level of less than 2/4. Mettauer et al¹⁶ also reported a significant increase in peak VO_2 , stating that a patient increased 64% at maximal exercise and 56% at ventilatory threshold when patient's exercised at 50%

Figure 1. Search algorithm.

of their maximum heart rate. Additionally, there were increases of oxygen saturation noted during exercise.¹⁶

Functional Independence Measure

Improvement in FIM scores in response to exercise were explored by Nissinoff et al.¹ This paper included a report on 3 patients after LVAD implantation. Comorbidities for the 3 patients included a mixture of hypertension, diabetes mellitus, end-stage renal disease, history of coronary artery bypass graft surgery, automatic implantable cardiac defibrillator placement, morbid obesity, and tricuspid valve repair. The length of stay for each patient was 7, 18, and 9 days respectively. The FIM gains varied from 1.0 to 4.6 per day, during an average length of stay of 27 days when an LVAD flow rate above 4 L/min and a MAP of 70-95 mm Hg were maintained during exercise.¹

Blood pressure response

The article by Kohli et al¹⁷ describes an adaptive MAP response to exercise, in patients with LVAD, as an increase from 87 ± 8 to 95 ± 13 ($p < 0.001$). Mean arterial pressure also had a positive correlation with METs achieved during exercise for these patients (MAP: $\beta = 0.26$; $p = 0.04$) when using parameters of 'as tolerated' noted by a Borg RPE rating less than 13/20 and a Dyspnea Scale less than 5/10.¹⁷ Patients involved in this study possessed comorbidities of diabetes mellitus, hypertension, and previous cardiac surgery.

Table 4. Summary of LVAD Exercise Parameters and Outcomes

Author/Date	Humphrey R, 1998 ¹⁴	Mettauer B, 2000 ¹⁶	MorroneTM, 1996 ¹⁵	Nissinoff J, 2011 ¹	Kohli HS, 2011 ¹⁷	de Jonge N, 2001 ⁷
Age Range	• Not available	• 61	• 52 ± 10	• 51,75,62	• 51.2 ± 13.6	• 37 ± 12
Study Design	• Expert Opinion	• Retrospective • Case Study • n=1	• Retrospective • Case Series • n=34	• Retrospective • Case Series • n=3	• Retrospective • Case Controlled Study • n=49	• Retrospective • Case Controlled Study • n=15
Sackett's Level of Evidence	• 5	• 4	• 4	• 4	• 3b	3b
Type of LVAD	• TCI Heartmate Pulsatile	• TCI Heart Mate 1000 IP • Pulsatile • Fill to empty mode	• TCI Heartmate • Pulsatile • "pump on full" mode	• VentrAssist LVAD and Heartmate II Centrifugal	• Heartmate II • Centrifugal	• TCI HeartMate • Pulsatile
Exercise Parameter	• 50% - 60% of METS achieved on exercise test • Borg RPE scale 11-13	50 % of peak HR	• 3.2 ± 0.79 METs • Borg 11-13/20	• MAP 70-95 mm Hg	• "As tolerated" • Borg<13/20 • Dyspnea Scale<5/10	• Borg < 4/10 • Exertional dyspnea < 2/4
Guidelines for terminating Exercise or Exercise Testing	<ul style="list-style-type: none"> • Achievement of 5 METS • Onset of Angina • Drop in SBP with increasing workload or drop below resting standing SBP • SBP >200 mmHg • DBP>115 mmHg • ECG changes: ST shifts>1mm; Increasing ventricular arrhythmias • O₂ desaturation <85% • Borg >13 for submaximal assessment; >16 for symptom-limited assessment • Symptomatic flow<3 L/min 	• None provided	• SBP drop >20 Symptomatic Flow <3 L/min	• A LVAD flow rate <4 L/min	• Orthostasis • Ataxia Symptoms of exercise intolerance	None provided

Therapeutic Intervention	<ul style="list-style-type: none"> Positioning and splinting Suctioning, chest PT, incentive spirometry Bedside mobility, transfers, range of motion of upper extremity as tolerable Ambulation Strengthening using elastic bands and weights <p>Education</p>	<ul style="list-style-type: none"> 6 week training program: Daily 20-30 minute stationary bicycle Constant rate exercises Encouraged to walk daily Daily respiratory kinesitherapy and light calisthenics 	<ul style="list-style-type: none"> Progressive mobilization leading to treadmill exercise and cycling 	<ul style="list-style-type: none"> Upper and Lower extremity ROM and strengthening exercises Transfer training Progressive gait training Energy conservation in ADL 	<ul style="list-style-type: none"> 5day/wk Progression of gait training on a functional goal of less than minimal resistance with transfers/ambulation Ambulation distance progressed toward goal of ≥ 600ft or 10 minutes continuously without adverse signs or rest breaks Endurance exercises on a treadmill or upper/lower extremity recumbent stepper Frequency of cardiac rehab was set at 3-5 days/week Exercise duration initially set at 5-10 minutes with gradual progression of 1-5 minutes per session, towards goal of ≥ 30 minutes of continuous aerobic activity 	<ul style="list-style-type: none"> Initial treatments: 2 to 6 minutes of low-level activities; alternated with 1 to 2 minutes of rest. Duration of exercise gradually increased from 20 to 40 mins/day for 3 to 5 times per week. Training includes sessions on the bicycle, treadmill, and rowing machine. Coordination is improved with badminton, tennis, and volleyball. Strength and endurance training of local muscle groups, according to the 5BX plan of the Royal Canadian Air Force.
Exercise initiation after implantation	<ul style="list-style-type: none"> As soon as is feasible, preferably the day following implantation Progressive exercise program once patient is able to ambulate independently 	<ul style="list-style-type: none"> Exercise training program initiated at 3 weeks post implantation 	<ul style="list-style-type: none"> Physical therapy initiated in the ICU as early as the first day (chest PT, ROM, and positioning) Ambulation initiated once patient showed adequate muscle strength (minimum 3/5) in LE muscles 	<ul style="list-style-type: none"> Initiated within first postoperative day, and when the patient was hemodynamically stable 	<ul style="list-style-type: none"> Off intravenous vasopressors Extubated from mechanical ventilation Of appropriate mental status 	<ul style="list-style-type: none"> Interval training began 2 weeks post-implantation
Adverse effects	<ul style="list-style-type: none"> None linked to exercise noted 	<ul style="list-style-type: none"> None linked to exercise noted <p>Death 103 days after implantation due to device malfunction</p>	<ul style="list-style-type: none"> 4 minor incidents involved an acute decrease in pump flow, where 3 of 4 were symptomatic 	<ul style="list-style-type: none"> None linked to exercise noted One death 2 months after discharge due to intracranial hemorrhage One death 7 months after discharge due to CHF exacerbation One death 21 days after discharge due to intracranial hemorrhage 	<ul style="list-style-type: none"> None linked to exercise noted Three patient deaths before PT initiated (3 to 78 days) 	<ul style="list-style-type: none"> None linked to exercise noted One death 133 days after implantation due to device failure One death 432 days after implantation due to repeated cerebral embolism

Outcomes	<ul style="list-style-type: none"> • LVAD patients respond well to graded exercise therapy • Adjustments should be made in exercise based on symptomatic responses • Early mobilization and progressive training is safe and improves transplantation experience 	<ul style="list-style-type: none"> • Peak VO_2 increased by 64% 	<ul style="list-style-type: none"> • Independent ambulation achieved by 82%, 55% by POD 14. • Treadmill exercise tolerated by 82% <p>At maximum, patients were able to train for 20-30 minutes at a mean workload of 3.2 ± 0.79 METs</p>	<ul style="list-style-type: none"> • Case 1 FIM rating: 76- >108 • Case 2 FIM rating: 66- >84 • Case 3 FIM rating: 67- >98 • Length of Stay efficiency improved, averaging 3.0 • LVAD flow average increase 	<ul style="list-style-type: none"> • Increase MAP with with treadmill exercise (87 ± 8 vs 95 ± 13; $p < 0.001$) <p>MAP correlated positively with METs (MAP: $\beta = 0.26$, $p = 0.04$)</p>	<p>8 weeks:</p> <ul style="list-style-type: none"> • Peak $\text{VO}_2 = 21.3 \pm 3.8$ • $\text{AT} = 14.8 \pm 2.2$ • $\text{VE}/\text{CO}_2 = 39.4 \pm 10.1$ • $\text{RQ} = 1.2 \pm 0.1$ <p>12 weeks:</p> <ul style="list-style-type: none"> • Peak $\text{VO}_2 = 24.2 \pm 4.8$ • $\text{AT} = 15.8 \pm 4.0$ • $\text{VE}/$ • $\text{CO}_2 = 36.8 \pm 8.2$ <p>$\text{RQ} = 1.2 \pm 0.1$</p>
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Exercise tolerance

Morrone et al¹⁵ discuss the increase in tolerance to exercise in patients with LVAD. Independent ambulation was achieved by 82% of patients in their study; of which 55% were independent by postoperative day (POD) 14. Treadmill exercise was also achieved by 82% of their patients, with 64% performing treadmill exercise by POD 21. Ambulation was initiated in the intensive care unit once patients showed adequate muscle strength (minimum 3/5) in selected lower extremity muscles. These patients were able to train for 20 to 30 minutes at a mean workload of 3.2 ± 0.79 METs.¹⁵ Morrone and colleagues¹⁵ did not specify how METs were determined during their study. Additional exercise parameters used by this patient group includes a Borg RPE scale rating of 11-13/20, maintaining a systolic blood pressure with no drop greater than 20 mmHg or maintaining LVAD flow greater than 3 L/min. Overall the average length of stay for these patients was 101 ± 72 days.

Safety/Adverse Effects

Out of the 6 studies reviewed, only one reported adverse effects in 4 out of 32 patients.¹⁵ Morrone et al¹⁵ reported 4 'minor incidents' involving a decrease in pump flow that did not result in a change of patient morbidity or mortality.¹⁵ Among the other articles, there were no adverse effects requiring life saving measures or alterations in medical treatment.

DISCUSSION

The success of LVAD placement has greatly enhanced the surgical management for patients awaiting a heart transplant, reducing the risk of death in end-stage heart failure patients by 50% at 6 and 12 months status post-transplant and extending the average life span from 3.1 to more than 10 months.¹⁸ Given the increased utilization of LVADs, it is important that physical therapists in the inpatient setting are knowledgeable of effective exercise guidelines in order to provide optimal management for these patients. The purpose of this study therefore, was

to systematically review the available literature, using PRISMA guidelines, with the intent to establish safe and effective exercise parameters for the rehabilitation of patients with LVADs in early postoperative stages. The use of these guidelines improves the overall quality of reporting standards of systematic reviews and meta-analyses. Overall agreement amongst reviewers during this search was high at 0.987 (95% CI 0.962 to 0.993).

The studies included in this review all indicate that cardiac rehabilitation is safe for these patients as early as two weeks status post implantation, based upon a patient's status as defined by the individual study (Table 4). Parameters regarding safe and effective exercise include: Borg RPE scale of no greater than 13/20 without onset of signs and symptoms of angina, electrocardiogram (ECG) changes including ST shifts no >1 mm and/or no increasing ventricular arrhythmias, dyspnea no greater than 5/10, claudication no greater than 2/4, decreased oxygen saturation, orthostasis, ataxia, and significant changes in systolic blood pressure. Additionally patients exercised safely when their MAP was maintained between 70 – 90 mmHg and LVAD flow remained above 3 L/min (Table 4).

Patients implanted with a VAD demonstrate similar presentations to patients with congestive heart failure (CHF), except patients with VAD use a mechanical device for hemodynamic support. The results of our systematic review parallel those found in multiple studies discussing the effects of exercise training on patients with CHF. Increased quality of life, decreased heart failure related to hospital admissions, and no increase in overall risk of mortality have been associated with exercise in the CHF population.¹⁹ Intensity limitations for patients with CHF include Borg RPE scale ratings ranging from 11-14 on the 6-20 scale²⁰⁻²² without adverse patient symptomology.²⁰ This corresponds with the exercise limitations of LVAD patients listed as 11-13 on the 6-20 Borg RPE scale resulting in no adverse effects.

A unique parameter for monitoring exercise tolerance in this population is LVAD flow, which is the mechanical

equivalent to cardiac output or stroke volume.²³ In patients with continuous flow pumps, such as the Heartmate II LVAS it is recommended by the manufacturer (Thoratec) to maintain a pump flow greater than 3 liters per minute with the device set to alarm if the flow drops below 2.5 liters per minute.²⁴ The recommendation reported in the Nissinoff¹ paper follows this parameter with their recommendation of maintaining flows above 4 liters per minute during exercise. For patients implanted with the TCI Heartmate, which are pulsatile flow pumps, the studies^{14,15} reported in this review also recommend maintaining LVAD flow above 3 liters per minute during exercise. Currently the TCI Heartmate is not on the market as continuous flow pumps appear to be more commonly used devices for patients with end-stage heart failure.^{5,25,26} The Heartmate XVE LVAS has been reported in the literature to be in use as a pulsatile device for patients who are bridge to transplant candidates.^{23,27} The Heartmate XVE has a pump rate of 50-120 beats per minute with a maximum stroke volume of 83 ml.²⁸ In this systematic review, no parameters for exercise were found using this specific LVAD device and according to the manufacturer, the Heartmate XVE is also no longer on the market.^{26,29} Subsequently there is more likelihood that clinicians in the acute care setting will encounter patients with newly implanted continuous LVAD devices.

Some differences regarding exercise parameters exist with patients who are status post VAD implantation compared to patients with CHF. Several articles studied report the use of VO_2 max as a parameter for exercise intensity in patients with CHF. A systematic review addressing safe exercise intensity reports varying percentages ranging from 40% to 70% peak VO_2 .²⁰ However, a percentage of peak VO_2 was not used as a limit to exercise for patients post VAD placement (Table 4). Additionally, heart rate has been used as an exercise parameter in patients with CHF. McConnell et al²² states that patients with CHF should remain between 60% to 80% of peak HR. Although one of the studies in our review lists 50% of peak HR as a beneficial intensity,¹⁶ this is not feasible for all patients with LVAD since HR can only be monitored in patients with pulsatile pumps and cannot be monitored for patients with a centrifugal or continuous pump. A better option for patients with a continuous pump would be to monitor tolerance to exercise via ECG changes, Borg RPE scale or MAP.^{1,17}

Limitations

Limitations of our study were that a small number of studies, written in English, were included in the review (n=6). Additionally, with respect to rating the level of evidence, the authors were unable to discriminate between articles with the same study design or assess for risk of bias using Sackett's level of evidence. This scale was chosen to rate the level of evidence because the articles included in our review could not be evaluated by Grading of Recommendations Assessment, Development and Evaluation (GRADE) due to the type of evidence that was available through our search. The GRADE system analyzes different types of studies and ranks them into 4 different

categories which are high, moderate, low, and very low. It also classifies recommendations as strong or weak based upon the quality of the evidence.³⁰ Also, while our review included studies with both pulsatile and continuous flow pumps, it appears that there is a trend towards increased implementation of continuous flow pumps.^{5,25,26,29} The exercise parameters noted for pulsatile flow pumps in this review may no longer be applicable given the lifespan of the older devices, such as the TCI Heartmate. Lastly, the articles included in our research focused only on patients with a LVAD; therefore, these exercise parameters cannot be generalized to patients with right or biventricular assist devices.

CONCLUSION

The available evidence is not strong enough to draw conclusive clinical guidelines for patients status post LVAD placement in acute care or rehabilitation settings. However, these retrospective case series and consensus statement articles do provide a point of reference to advise clinical practice. Furthermore, since little to no adverse outcomes were reported during exercise when using the parameters or exercise endpoints as outlined in Table 4, our review suggests that it would be acceptable to use these parameters for patient status post LVAD implantation, in particular, those with continuous flow devices such as the Heartmate II LVAS.

Although there is research discussing the outcomes of patient's status post LVAD placement, safe and effective exercise parameters need to be explored for all types of VADs (eg, RVAD and BiVAD). Also, future research needs to be based on larger patient populations, with high quality studies including randomized control trials. It may be beneficial for future research to establish a standard protocol for exercise within this patient population.

REFERENCES

1. Nissinoff J, Tian F, Therattil M, Salvarrey RM, Lee SW. Acute inpatient rehabilitation after left ventricular assist device implantation for congestive heart failure. *PM R*. 2011;3(6):586-589.
2. Rose EA, Gelijns AC, Moskowitz AJ, et al. Long-term use of a left ventricular assist device for end-stage heart failure. *N Engl J Med*. 2001;345(20):1435-1443.
3. Salzberg S, Lachat M, Zund G, et al. Left ventricular assist device as bridge to heart transplantation - Lessons learned with the MicroMed DeBakey axial blood flow pump. *Eur J Cardiothorac Surg*. 2003;24:113-118.
4. Baughman KL, Jarcho JA. Bridge to life-cardiac mechanical support. *N Engl J Med*. 2007;357:846-849.
5. Miller LW, Pagani FD, Russel SD, et al. Use of continuous-flow device in patients awaiting heart transplantation. *N Engl J Med*. 2007;357:885-896.
6. Haft J, Armstrong W, Dyke DB, et al. Hemodynamic and exercise performance with pulsatile and continuous-flow left ventricular assist devices. *Circulation*. 2007;116(11 Suppl):18-15.

7. de Jonge N, Kirkels H, Lahpor JR, et al. Exercise performance in patients with end-stage heart failure after implantation of a left ventricular assist device and after heart transplantation: an outlook for permanent assisting. *J Am Coll Cardiol*. 2001;37:1794-1799.
8. Kugler C, Malehsa D, Tegbur U, et al. Health-related quality of life and exercise tolerance in recipients of heart transplants and left ventricular assist devices: a prospective, comparative study. *J Heart Lung Transplant*. 2011;30(3):204-210.
9. Liberati A, Altman DG, Tetzlaff J, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *BMJ*. 2009;339:b2700.
10. Slaughter MS, Rogers JG, Milano CM, et al. Advanced heart failure treated with continuous-flow left ventricular assist device. *N Engl J Med*. 2009;361:2241-2251.
11. Allen JG, Weiss ES, Schaffer JM, et al. Quality of life and functional status in patients surviving 12 months after left ventricular assist device implantations. *J Heart Lung Transplant*. 2010;29(3):278-285.
12. van der Wulp I, van Stel HF. Calculating kappas from adjusted data improved the comparability of the reliability of triage systems: a comparative study. *J Clin Epidemiol*. 2010;63:1256-1263.
13. Centre for Evidence-based Medicine. Levels of Evidence (March 2009) Website. Available at www.cebm.net. Accessed June 4, 2012.
14. Humphrey R, Buck L, Cahalin L, Morrone T. Physical therapy assessment and intervention for patients with left ventricular assist devices. *Cardiopulm Phys Ther J*. 1998;9(2):3-7.
15. Morrone TM, Buck LA, Catanese KA, Goldsmith RL, Cahalin LP, Oz MC, Levin HR. The journal of heart and lung transplantation; the official publication of the international society for heart transplantation. *J Heart Lung Transplant*. 1996;15(4):423-429.
16. Mettauer B, Geny B, Lonsdorfer-Wolf E, et al. Exercise training with a heart device: a hemodynamic metabolic, and hormonal study. *Med Sci Sports Exerc*. 2000;33(1):2-8.
17. Kohli HS, Canada J, Arena R, et al. Exercise blood pressure response during assisted circulatory support: comparison of the total artificial heart with a left ventricular assist device during rehabilitation. *J Heart Lung Transplant*. 2011;30(11):1207-1213.
18. Implantable Medical Devices. American Heart Association. http://www.heart.org/HEARTORG/Conditions/HeartAttack/PreventionTreatmentofHeartAttack/Implantable-Medical-Devices_UCM_303940_Article.jsp. Accessed June 9, 2012.
19. Davies EJ, Moxham T, Rees K, et al. Exercise based rehabilitation for heart failure (Review). *Cochrane Database Syst Rev*. 2010;4:1-73.
20. Pina IL, Apstein CS, Balady GJ, et al. Exercise and heart failure: a statement from the American Heart Association committee on exercise, rehabilitation, and prevention. *Circulation*. 2003;107:1210-1225.
21. Carvalho VO, Mezzani A. Aerobic exercise training intensity in patients with chronic heart failure: principles of assessment and prescription. *Eur J Cardiovasc Prev Rehabil*. 2011;18(1):5-14.
22. McConnell TR. A review to develop an effective exercise training for heart failure patients. *Eur J Phys Rehabil Med*. 2005;41(1):49-56.
23. Nicholson C, Paz J. Total Artificial Heart and Physical Therapy Management. *Cardiopulm Phys Ther J*. 2010;21(2):13-21.
24. Heartmate II Left Ventricular Assist Operating Manual. <http://www.thoratec.com/medical-professionals/resource-library/index.aspx>. Accessed August 2, 2012.
25. Maniar S, Kondareddy S, Topkara VK. Left Ventricular assist device-related infections: past, present and future. *Expert Rev Med Devices*. 2011;8(5):627-634.
26. VAD Product Information (USA). Thoratec Corporation. <http://www.thoratec.com/medical-professionals/vad-product-information/index.aspx>. Accessed August 2, 2012.
27. Elhenaway AM, Algarni KD, Rodger M, et al. Mechanical circulatory support as a bridge to transplant candidacy. *J Card Surg*. 2011;26(5):542-547.
28. Heartmate XVE LVAS Operating Manual. <http://www.thoratec.com/medical-professionals/resource-library/index.aspx>. Accessed August 10, 2012.
29. Personal communication with Thoratec Corporation August 10, 2012; (800) 456-1477. <http://www.thoratec.com/about-us/contact-us.aspx>
30. Guyatt GH, Oxman AD, Vist GE, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ*. 2008;336(7650):924-926.