Rev Esp Cardiol. 2017;xx(x):xxx–xxx

Original article

Left Ventricular Assist Device Therapy for Destination Therapy: Is Less Invasive Surgery a Safe Alternative?

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Article history:
Received 11 July 2016
Accepted 16 March 2017

Keywords:
Left ventricular assist device
Mechanical circulatory support
Minimally invasive
Less invasive
Surgical technique
Destination therapy

ABSTRACT

Introduction and objectives: The number of older patients with congestive heart failure has dramatically increased. Because of stagnating cardiac transplantation, there is a need for an alternative therapy, which would solve the problem of insufficient donor organ supply. Left ventricular assist devices (LVADs) have recently become more commonly used as destination therapy (DT). Assuming that older patients show a higher risk-profile for LVAD surgery, it is expected that the increasing use of less invasive surgery (LIS) LVAD implantation will improve postoperative outcomes. Thus, this study aimed to assess the outcomes of LIS-LVAD implantation in DT patients.

Methods: We performed a prospective analysis of 2-year outcomes in 46 consecutive end-stage heart failure patients older than 60 years, who underwent LVAD implantation (HVAD, HeartWare) for DT in our institution between 2011 and 2013. The patients were divided into 2 groups according to the surgical implantation technique: LIS (n = 20) vs conventional (n = 26).

Results: There was no statistically significant difference in 2-year survival rates between the 2 groups, but the LIS group showed a tendency to improved patient outcome in 85.0% vs 69.2% (P = .302). Moreover, the incidence of postoperative bleeding was minor in LIS patients (0% in the LIS group vs 26.9% in the conventional surgery group, $P < .05$), who also showed lower rates of postoperative extended inotropic support (15.0% in the LIS group vs 46.2% in the conventional surgery group, $P < .05$).

Conclusions: Our data indicate that DT patients with LIS-LVAD implantation showed a lower incidence of postoperative bleeding, a reduced need for inotropic support, and a tendency to lower mortality compared with patients treated with the conventional surgical technique.

Asistencia ventricular izquierda como terapia de destino: ¿la cirugía mínimamente invasiva es una alternativa segura?

Palabras clave:
Dispositivo de asistencia ventricular izquierda
Soporte mecánico circulatorio
Mínimamente invasivo
Menos invasivo
Técnica quirúrgica
Terapia de destino

RESUMEN

Introducción y objetivos: El número de pacientes ancianos con insuficiencia cardiaca terminal ha crecido espectacularmente. Considerando que el número de trasplantes cardiacos se ha estancado, se requiere una alternativa terapéutica. Desde hace poco se están aplicando como terapia de destino (TD) dispositivos de asistencia ventricular izquierda (DAVI). Asumiendo que los pacientes de más edad tienen mayor riesgo quirúrgico, es presumible que la cirugía menos invasiva (CMI) para el DAVI contribuya a mejorar los resultados operatorios en pacientes en TD.

Métodos: Se realizó un estudio prospectivo con un seguimiento de 2 años de 46 pacientes en TD (edad mayor de 60 años) consecutivos a los que se trató con DAVI (HVAD, HeartWare) en nuestra institución entre 2011 y 2013. Se formaron 2 grupos según el método quirúrgico de implante: CMI (n = 20) o cirugía convencional (n = 26).

Resultados: A pesar de que no se hallaron diferencias estadísticas significativas respecto a la supervivencia a 2 años, sí se observó una tendencia a mayor supervivencia en el grupo CMI (el 85,0 frente al 69,2%; p = 0,302). Asimismo, los pacientes del grupo de CMI presentaron menor

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http://dx.doi.org/10.1016/j.rec.2017.03.023

Please cite this article in press as: Rojas SV, et al. Left Ventricular Assist Device Therapy for Destination Therapy: Is Less Invasive Surgery a Safe Alternative? *Rev Esp Cardiol.* 2017. http://dx.doi.org/10.1016/j.rec.2017.03.023

incidencia de hemorragias tras la cirugía (0 frente al 26,9%; p < 0,05), junto con menores tasas de uso prolongado de inotrópicos tras la cirugía (el 15,0 frente al 46,2%; p < 0,05).
Conclusiones: Los datos indican que los pacientes sometidos a CMI para implante de DAVI como TD muestran tras la cirugía menor incidencia de hemorragias, menor necesidad de apoyo con inotrópicos y una tendencia a menor mortalidad que los pacientes operados de manera convencional.

Abbreviations

DT: destination therapy
ECMO: extracorporeal membrane oxygenation
LIS: less invasive surgery
LVAD: left ventricular assist device

INTRODUCTION

Modern conservative therapies for heart failure have improved outcomes in adult patients.[1] Despite medical advances in treating this condition, the disease itself remains a progressive condition. Projections estimate that by 2020 the number of patients dying from cardiovascular disease will increase to more than 7 millions worldwide.[2,3] Cardiac transplantation as a therapeutic option is strongly restricted by donor organ shortage and is therefore mainly limited to patients younger than 60 years.[4,5] In times of demographical changes, reflected in population aging, there is an urgent need for alternative and effective therapies to treat end-stage heart failure in elderly patients.[6] Thus, left ventricular assist devices (LVADs) are now widely applied as destination therapy (DT).[7–13] However, DT patients have an increased perioperative risk with high mortality.[8] In their seminal article, Slaughter et al.[14] showed that the treatment with continuous-flow LVAD improved the survival of DT patients by up to 58% after 2 years of being on pump. In that study, all patients were underwent the standard surgical technique, which is by a full sternotomy. At that time, this surgical approach was mandatory due to the increased pump size and the lack of surgical alternatives. Of note, a full sternotomy involves major operative trauma with higher risks of postoperative respiratory failure, longer intrahospital stay, and perioperative bleeding.[15–17] In LVAD surgery, it is especially critical to avoid bleeding, since the therapy itself involves alterations of hemostasis, such as acquired von Willebrand syndrome, which also increases the perioperative bleeding risk.[18] According to a literature review, the incidence of bleeding requiring surgery and extended inotropic support ranges from 30% to 40% in DT patients undergoing by full sternotomy.[14,19–21] Moreover, a full sternotomy implies a full opening of the pericardium, which abrogates the natural confinements of the right ventricle, thus contributing to the danger of postoperative right heart failure once LVAD is started.[22]

A key feature of the newest LVADs is their remarkably reduced pump size.[23,24] This has facilitated the development of less invasive surgery (LIS) techniques for the implantation, explantation, and exchange of ventricular assist devices.[25–28] The new era of LIS-LVAD implantation is expected to improve therapy outcomes by reducing such important operative complications as bleeding or right ventricular failure.[29,30]

This study reports the first long-term results of DT patients with end-stage heart failure undergoing a minimally invasive technique for continuous-flow pump implantation.

METHODS

In 2011, our group developed a minimized LVAD implantation technique.[22] Between 2011 and 2013, we performed a prospective study of 46 consecutive patients older than 60 years, who required LVAD surgery as DT because they were ineligible for cardiac transplantation. All patients were operated on by the same surgical team that decided which technique to use for implantation. The data of 20 patients that received LIS-LVAD implantation (HVAD, HeartWare Inc, Miami Lakes, United States) were compared with those of a control group of 26 patients who underwent conventional sternotomy. Clinical indication criteria for LVAD implantation were as follows: significantly impaired cardiac function (left ventricular ejection fraction $< 30\%$) with cardiac index < 2.2 L/min/m^2 refractory to medical therapy, including inotrope dependency. All patients with previous cardiac surgery and/or concomitant cardiac surgery were excluded from the study. Extended inotropic support was defined as inotropic therapy for ≥ 14 days after LVAD implantation. Respiratory failure was defined as pulmonary insufficiency requiring intubation and ventilation for a period of 96 hours or more at any time during the postoperative stay due to blood oxygen saturation $< 96\%$ while receiving a fraction of inspired oxygen ≥ 0.50. Renal failure was defined by the need for dialysis.

The LIS procedure involves 2 steps: first, the LVAD pump is inserted through an anterolateral thoracotomy (fifth or sixth intercostal space). Second, the surgical team performs an upper J-shaped hemisternotomy to the third intercostal space to anastomose the LVAD outflow graft end-to-side to the ascending aorta.[22] Finally, all patients received the same LVAD system (HVAD, HeartWare) and were implanted using cardiopulmonary bypass. The implantation was followed by a 2-year follow-up, during which the patients visited the outpatient clinic 4 times a year.

The investigation conforms to the principles outlined in the Declaration of Helsinki. All patients provided written informed consent and the study was approved by the local institutional review board. Postoperative medical care was maintained according to usual practice.

Statistical Analysis

The statistical analysis was performed using SPSS 20.0 (IBM SPSS Statistisics, IBM Corp, Armonyk New York, United States). We used unpaired *t* test, the Fisher exact test, the Pearson chi-square test, and the Kaplan-Meier survival estimation for statistical analysis. Survival curves were compared using the log-rank test. Differences were considered significant at $P < .05$. All continuous data are summarized as mean ± standard deviation.

RESULTS

Baseline characteristics are summarized in Table 1 and were similar in both patient groups. There was a predominance of men with mean preoperative ejection fractions measured by

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