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ORIGINAL ARTICLE

Efficacy and Safety of Inter-Atrial Shunt Devices for Heart Failure With Reduced or Preserved Ejection Fraction: Early Experiences

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Background Elevated left atrial (LA) pressure is thought to be the common final pathological way in decompensated heart failure (HF). We aimed to gather currently available clinical evidence to evaluate the feasibility of inter-atrial shunt devices in HF patients.

Methods We searched PubMed and Cochrane Library databases through 23rd April 23, 2016. Data were extracted by two investigators independently. We pooled outcomes of interest in Revman 5.2 (The Cochrane Collaboration, Oxford, United Kingdom).

Results A total of four records were identified in the final review, involving HF patients with reduced ejection fraction (EF) and those with preserved EF. Pooled analysis showed that pulmonary capillary wedge pressure significantly reduced after inter-atrial shunt devices implantation, with a mean difference (MD) of −3.54 mmHg (95% confidence interval [CI] = −5.63 to −1.45 mmHg) and low heterogeneity (I^2 = 16%), 6-min walk distance significantly increased, with a MD of 36.84 m (95% CI = 3.52 to 70.16m) and low heterogeneity (I^2 = 0%), and Minnesota Living with Heart Failure score significantly improved (MD = −22.99 with 95% CI −44.45 to −1.52) following shunting. No evidence of worsening pulmonary hypertension was observed in these studies. No device-related deaths, thrombo-embolic or cardiac events were recorded during follow-up.

Conclusions Current evidence suggests that inter-atrial shunting might be a potential and promising therapy for HF, regardless of the ejection fraction.

Keywords Heart failure • Inter-atrial shunt • Left atrial pressure • Pulmonary capillary wedge pressure

Introduction

Heart failure (HF) is a common malignant disorder, accompanied by high mortality and morbidity [1,2]. As the population ages, the prevalence of HF will continue increasing [3]. Increase of morbidity of comorbid diseases such as hypertension, ischaemic heart disease and diabetes may also contribute to the high prevalence of HF [4,5]. For patients with HF and reduced ejection fraction (HFrEF), drug therapies such as angiotensin-converting-enzyme inhibitors, β blockers and spironolactone are widely used. However, in many patients, despite the use of these drugs, the poor

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quality of life, high frequency of HF-related hospitalisation and mortality persist and even deteriorate [2]. Therefore, interventional treatments of HF are gaining attention. Cardiac resynchronisation therapy (CRT) helps to improve symptoms and reduce mortality of HF in selected patients [i.e. left ventricular ejection fraction (LVEF) ≤35% and complete left bundle branch block (LBBB)]; however, only a small proportion of HF patients (probably 5–10%) are suggested for CRT [6]. Approximately 50% of HF patients have a preserved ejection fraction (HFpEF) [7], and to the present, there is no substantiated effective treatment for HFpEF.

Increased left atrial (LA) pressure is thought to be the common final pathological way to cause decompensated HF symptoms [8]. This provides a rationale for the use of a left-to-right interatrial shunt device (IASD) as a novel treatment for HF. In the past few years, several case reports have reported that IASD to decompress LA could bring encouraging results [9,10]. We aimed to gather currently available clinical evidence to evaluate the feasibility of IASD in HF patients.

Methods

We searched PubMed and Cochrane Library through 23rd April 23, 2016. We also reviewed relevant references of articles. A literature search was conducted by two separate investigators. ''Heart failure'' or ''cardiac failure'' and ''interatrial shunt'' or ''interatrial device'' were applied as search terms. The titles and abstracts were independently scanned by two researchers, and potential eligible publications was carefully reviewed in full text. Articles reporting the use of inter-atrial shunt device in HF patients were considered potentially eligible. Detailed inclusion criteria were as follows: 1) inter-atrial shunt device was implanted in HF patients; 2) cardiac function and/or haemodynamics and/or exercise capacity test were reported at both baseline and follow-up; 3) number of participants should be no less than five; and 4) human clinical study. No language restriction was applied. Case reports and duplicate reports were excluded. We applied the Newcastle-Ottawa Scale to evaluate the quality of included studies (Supplementary Table 1).

The primary efficacy endpoints were changes in pulmonary capillary wedge pressure (PCWP, exercise PCWP was included if available), functional capacity (6-min walk distance), echocardiographic indices, quality of life scores and natriuretic peptides at follow-up periods from baseline. The primary safety endpoints were defined as major adverse cardiac and cerebrovascular events, such as death, stroke, myocardial infarction, or a systemic embolic event during procedure and follow-up periods. Data were extracted by two investigators independently. Characteristics of included studies and subjects were reviewed and extracted. We pooled outcomes of interest in Revman 5.2. Mean difference (MD) with 95% confidence interval (CI) was applied to compare the differences between baselines and follow-up. Heterogeneity was assessed by I square test, I^2 value of 25%, 50%, 75% stood for low, modest, high heterogeneity, respectively. A fixed-model was used when $I^2 < 50$, otherwise, a random-effects was applied. $P < 0.05$ was taken as significant difference.

Results

There were 117 records in our initial retrieval result, and a total of four records were identified in the final review [11–14], of which two records reported the same study with a different follow-up [13,14], and we treated these two publications as one. The study by Del Trigo et al. used a V-Wave inter-atrial shunt device in patients with HFrEF [11], while Hasenfu et al. [12] and Sondergaard et al. [14] applied a stent-like inter-atrial shunt device in patients with HFpEF. Shunt implantation was performed percutaneously via the femoral vein access. All these studies were characterised as non-randomised, open-label and single-arm. Pulmonary capillary wedge pressure (PCWP) was assessed by right-heart catheterisation at baseline and follow-up. Echocardiography, 6-min walk test and quality of life assessment were performed at baseline and follow-up. The baseline characteristics of included subjects are summarised in Table 1. Table 2 shows the inclusion criteria and peri-procedural characteristics of included studies. The follow-up varied from 30 days to 12 months; we considered follow-up ≤ 6 months as short-term, and follow-up duration >6 months as long-term, the endpoints of interest at different follow-ups were reviewed and compared separately.

Changes in PCWP From Baseline to Follow-up

All the three studies reported a reduction in PCWP at rest or during exertion from baseline to follow-up. Pooled analysis showed that PCWP was significantly reduced following IASD, with a MD of −3.54 mmHg (95% CI = −5.63 to −1.45 mmHg) and low heterogeneity (I^2 = 16%) (Figure 1A). No evidence of worsening pulmonary hypertension was observed in these studies. Right ventricular function, as reflected by tricuspid annular plane systolic excursion (TAPSE) was unchanged at follow-up (p = 0.75).

Changes in 6-Minute Walk Distance and Quality of Life

At short-term follow-up (≤6 months), pooled analysis showed that 6-min walk distance significantly increased, with a MD of 36.84 m (95% CI = 3.52 to 70.16m) and low heterogeneity (I^2 = 0%) (Figure 1B). However, at long-term follow-up (12 months), a non-significant increase in 6-min walk distance was observed (from 315 ± 152 m to 343 ± 76m,

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