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Original Article

Therapeutic potential of sildenafil in patients with chronic heart failure after cardiac surgery



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ABSTRACT

Background: Previous studies have demonstrated hemodynamic and clinical benefits associated with chronic inhibition of 5-phosphodiesterase with sildenafil therapy for heart failure patients. However, its effects in refractory heart failure following cardiac surgery are unknown.

Objective: To evaluate the clinical benefits of sildenafil addition to standard therapy in patients with advanced (refractory) heart failure after cardiac surgery.

Methods: A prospective single-arm study which was done on 26 patients with refractory heart failure after cardiac surgery despite receiving the standard anti-failure treatment, from September 2012 to June 2013. Patients were included into one group and were evaluated before and after 1, 2 and 3 months of sildenafil addition to the standard anti-failure treatment. **Results:** Add-on sildenafil treatment resulted in significant increase in cardiac output, ejection fraction and fractional shortening, with significant decrease in left ventricular systolic internal diameter, end systolic volume, right ventricular pressure and pulmonary hypertension. Consistently, there were significant improvements in signs and symptoms of heart failure, New York Heart Association Class, with marked improvement in the patients' clinical status. There were no significant changes in heart rate, left ventricular diastolic internal diameter and end diastolic volume. There were no significant adverse events and the reported four cases of mortality (15.4%) were died due to different causes and none was associated with sildenafil therapy.

Conclusion: We demonstrated that sildenafil use improves signs and symptoms of heart failure, NYHA class, echocardiographic parameters and quality of life in patients with refractory heart failure following cardiac surgery.

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1. Introduction

Chronic heart failure is a syndrome of heart impairment which leads to decrease in cardiac output and disability to

cover metabolic demands of tissues, this dysfunction may be systolic and/or diastolic¹ and it is considered as a major problem in the long term follow-up after cardiac surgery.²

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The long-term, or chronic complications of the surgery are; return of angina and myocardial infarction after CABG, recurrent mitral regurgitation, atrial and ventricular fibrillation, LV dysfunction, pulmonary hypertension, RV dysfunction and endothelial dysfunction. Endothelial dysfunction is a well-recognized feature of heart failure, underlying mechanisms integrating vascular endothelium changes include increased systemic vascular resistance, contributing to reduced cardiac performance.³ Endothelial dysfunction in heart failure is associated with reduced vascular nitric oxide release.⁴

Advanced or refractory heart failure can be defined as the persistence of symptoms that limit daily life (functional class III or IV of the New York Heart Association NYHA Classification) despite optimal previous treatment with drugs of proven efficacy for the condition.⁵ This refers to patients with advanced structural heart disease and severe signs of heart failure at rest with a progressive course of increasing symptoms, recurrent hospitalizations, and shortened survival, all likely mediated by ventricular remodeling.⁶ They are candidates for other specialized interventions, such as heart transplantation, implantation of mechanical assistance devices or the administration of intravenous inotropic drugs.⁷

Sildenafil citrate is the first licensed oral phosphodiesterase type 5 inhibitor.⁸ It is a potent selective inhibitor of cGMP-specific PDE-5 (which is present in vascular bed). This isoenzyme metabolize cGMP, which is the second messenger of NO and a principle mediator of smooth muscle relaxation. By inhibiting the breakdown of cGMP, sildenafil prolongs the action of cGMP, this results in augmented smooth muscle relaxation.⁹ Inhibition of phosphodiesterase 5 by sildenafil has shown to be beneficial by increasing nitric oxide availability to vascular bed,⁴ and improves parameters of endothelial and cardiac function in patients with heart failure.¹⁰

Clinical pharmacy services include: accurate medication reconciliation; developing patient care plans including the selection, dosing, and monitoring of drug therapy; promoting medication adherence; and educating patients and other health care providers regarding complexities of drug therapy. Clinical pharmacy services have been shown to reduce length of hospital stay, medication errors, adverse drug reactions, and costs, and to improve survival.^{11,12}

The aim of this study was to evaluate the clinical benefits of sildenafil addition to standard therapy in patients with advanced (refractory) heart failure after cardiac surgery.

2. Patients and methods

2.1. Study design

Prospective single-arm study.

2.2. Setting

The Echocardiography Clinic, Ain Shams University Hospitals, Cairo, Egypt.

2.3. Inclusion criteria

Adult patients (age 18–70 years) and had undergone valvular surgery or CABG and had advanced (refractory) heart failure after the surgery.

2.4. Exclusion criteria

Systolic arterial pressure less than 90 mmHg, history of intolerance to sildenafil, history of recent stroke or ischemic optic neuropathy, use of nitrates.

2.5. Method

All eligible patients received the standard therapy of heart failure which consisted of; Digoxin; 0.25 mg (Lanoxin[®]), GSK. 1 tablet/day; Captopril: 25 mg (Capoten[®]), EIPICO, 1–3 tablets/day; Furosemide; (Lasix[®]), Aventis, 1 tablet/day, plus Spironolactone: 25 mg (Aldactone[®]), Searle, 3 tablets/day or Hydrochlorothiazide: 50 mg (Moduretic[®]), El Kahira, 1 tablet/day.; In addition to Sildenafil: 25 mg of sildenafil citrate (Seldene[®]), EIPICO (2–3 tablets/day).

Each eligible patient was submitted to baseline evaluations which include:

- 1 **Patient's data** (name, age, gender).
- 2 **History taking** (type of operation, Date of operation, the anti-failure treatment the patient was taking).
- 3 **Clinical examination:**
 - **Hemodynamic data** (heart rate, systolic blood pressure, diastolic blood pressure).
 - **Symptoms of heart failure:**
 - a) **Pulmonary:** difficult and shortness of breath, cough, and coughing-up blood.
 - b) **Cardiac:** palpitations, chest pain.
 - c) **Systemic:** tiredness and fatigue, peripheral edema and ascites, nausea and lack of appetite.
 - **Signs of heart failure:**
 - a) **Pulmonary:** pulmonary congestion, tachypnea.
 - b) **Cardiac:** tachycardia, cardiac dilatation, LV hypertrophy, arrhythmias.
 - c) **Systemic:** peripheral edema, liver congestion, hepatomegaly, cyanosis.
- 4 **Functional class:** The severity of heart failure is most often classified into four functional classes using the NYHA classification
 - **Class I: No limitation of physical activity,** Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea. Patients can handle ordinary physical activity including walking or running 8 km/h.
 - **Class II: Slight limitation of physical activity,** Comfortable at rest, but ordinary physical activity results in fatigue, palpitation, or dyspnea. Patients can handle less than ordinary activity but ordinary activity results in fatigue or dyspnea.
 - **Class III: Marked limitation of physical activity,** Comfortable at rest, but less than ordinary activity results in fatigue, palpitation, or dyspnea. Patients suffer from dyspnea or fatigue during basic activity such as dressing or washing.

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