

Erectile dysfunction drug improves exercise tolerance in young people with congenital heart disease

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Sildenafil, a drug used to treat erectile dysfunction and pulmonary hypertension, has another possible use -- helping children and young adults with congenital heart disease to better tolerate exercise. Sildenafil significantly improved measures of exercise performance during stress testing in patients with single-ventricle heart disease, according to researchers from The Children's Hospital of Philadelphia.

This study was published online on March 7 in the journal *Circulation*. It is the first randomized, double-blind, placebo-controlled, crossover trial to evaluate the impact of sildenafil on measures of exercise performance in children and young adults with single-ventricle [heart disease](#).

All patients involved in the study had earlier undergone the Fontan operation, a procedure that redirects systemic venous blood directly to the [pulmonary arteries](#), bypassing the heart. It is the third operation in a staged series of surgeries for single-ventricle [heart defects](#), life-threatening conditions in which a child is born with severe underdevelopment of one of the pumping chambers of the heart.

"Despite dramatically improved early operative success achieved over the past 20 years, morbidity and mortality are still a challenge for children who have undergone a Fontan operation," said David J. Goldberg, M.D., pediatric cardiologist at The Children's Hospital of Philadelphia and primary investigator of this study. "The staged

palliation does not recreate a normal two-ventricle circulation; instead the series of surgeries creates a unique physiology in which [exercise capacity](#) is dramatically diminished."

In this study, researchers randomized 28 children and young adults who had undergone the Fontan operation an average of 11 years earlier to receive either placebo or sildenafil three times a day for 6 weeks. After a 6 week break from treatment, subjects were switched to the opposite treatment course. As a "proof-of-concept" study, the researchers selected a relatively healthy cohort of subjects without significant complications that they felt would have sufficient exercise capacity to complete the study.

The researchers found significant improvements in exercise performance during treatment with sildenafil compared to placebo. The findings included improved ventilatory efficiency and, in two subgroups of patients, an improved ability to perform moderate levels of exercise. These changes suggest an overall improvement in the physiology associated with this unique circulation.

"The enhanced exercise performance that we found in the study is exciting and may lead to an improvement in day-to-day activities for these children and young adults," Dr. Goldberg said. "However, it is important to note that while the results of this study are encouraging, more work is needed to determine whether the short-term benefit found in this study holds up over a longer period of time and whether there are any long-term side effects," he added.

"If the results from this preliminary study are validated in a larger sample over a longer period of time, it may be that this medication has the potential to improve quality of life for patients born with only one ventricle," Dr. Goldberg concluded.

Provided by Children's Hospital of Philadelphia

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