Many recent studies, most of them uncontrolled trials, suggest that sildenafil may be beneficial in the treatment of pulmonary arterial hypertension (PAH). A multicentre, double blind, placebo controlled study was performed in 278 patients with symptomatic PAH (either idiopathic, associated with connective tissue disease, or repaired systemic-to-pulmonary shunts). The patients were randomised into four treatment groups: placebo, 20 mg, 40 mg, and 80 mg sildenafil three times daily. The primary measure of efficacy was the change from baseline to week 12 in the distance walked in 6 minutes. An increase in the 6 minute walk distance was observed in all sildenafil groups, the mean placebo corrected treatment effects being 45 m (+13.0%), 46 m (+13.3%), and 50 m (+14.7%) with 20 mg, 40 mg, and 80 mg sildenafil, respectively (all \( p<0.001 \)). Cardiopulmonary haemodynamics and the WHO functional status also improved significantly with all doses of sildenafil. However, there was no statistical difference in the incidence of clinical worsening. With all doses of sildenafil, most adverse events observed were mild to moderate in severity and there were no significant changes in laboratory variables. This study was not, however, designed to address the important end point of mortality.

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