

**Sildenafil citrate in diabetes mellitus patients with erectile dysfunction
double blind placebo controlled crossover clinical trial**

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The objective of this study was to assess the efficacy, acceptability and side-effects of oral sildenafil citrate in diabetes mellitus patients with erectile dysfunction. 103 diabetic patients with erectile dysfunction who are attending the Endocrine Clinic at National Hospital of Sri Lanka were selected for the study. Sildenafil citrate 50mg or placebo was given to alternate patients and after a wash-out period of 2 weeks, those who were initially given the drug were given the placebo and vice versa. 5 item version of International Index of Erectile Function (IIEF-5) was used to assess the degree of erectile dysfunction. IIEF-5 was assessed before giving any treatment and after the placebo and the drug. Ninety five (92.3%) patients completed the study. There was a significant improvement ($P < 0.001$) in IIEF-5 after treating with sildenafil citrate (IIEF-5 mean 17.1) when compared with placebo (IIEF-5 mean 10.7). 48 (50.5%) patients had at least a single side-effect attributed to the drug. These adverse effects were transient and mild in nature including nasal congestion, gastrointestinal disturbances, visual disturbances, headache, dizziness and faintness in order of significance. 92 (96.8%) patients said that the use of sildenafil citrate was acceptable to them. It could be concluded that sildenafil citrate is an effective drug in the management of erectile dysfunction in diabetic patients. Side effects of sildenafil citrate are transient and mild. Patients expect clinicians to diagnose and treat erectile dysfunction appropriately.