Review: Sildenafil improves erectile dysfunction and is well tolerated

Fink HA, MacDonald R, Rutks IR, Nelson DB, Wilt TJ. **Sildenafil for male erectile dysfunction: a systematic review and meta-analysis.** Arch Intern Med. 2002;162:1349-60.

QUESTION

What is the efficacy and safety of sildenafil citrate (Viagra) in the treatment of erectile dysfunction?

DATA SOURCES

Studies were identified by searching MEDLINE, HealthSTAR, *Current Contents*, and the Cochrane Library (1995 to 2000); bibliographies of relevant studies and review articles; urology journals and conference proceeding abstracts; the Food and Drug Administration Web site; and by contacting the manufacturer of sildenafil.

STUDY SELECTION

Studies were selected if they were randomized controlled trials that compared sildenafil with a control treatment in men with erectile dysfunction, were ≥ 7 days in duration, and reported clinically relevant outcomes.

DATA EXTRACTION

Data were extracted by 2 independent reviewers on study quality, patient characteristics, treatment regimen, treatment efficacy, and adverse effects.

MAIN RESULTS

27 placebo-controlled trials involving 6659 men (mean age 55 y) met the selection criteria. 14 parallel-group, flexible as-needed dosing trials were pooled and showed that sildenafil led to a higher mean percentage of successful intercourse attempts, to a greater percentage of men having ≥ 1 intercourse success, and to improved erections (Table). Treatment response varied between patient subgroups, but in all instances sildenafil improved erectile function. Men receiving sildenafil were less likely to drop out from their assigned treatment for any reason (7% vs 14%), and the groups did not differ in drop-out rates because of adverse effects or laboratory abnormalities (1.3% vs 1.2%). Sildenafil was not associated with serious cardiovascular events or death. 6 parallel-group, fixed-dose trials were pooled and showed that sildenafil may be slightly more efficacious at higher doses (50 vs 25 mg).

CONCLUSION

Sildenafil improves erectile dysfunction and is well tolerated.

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Sildenfil (Sil) vs placebo for erectile dysfunction at 4 weeks before end of treatment assessment*

Outcomes	Sil	Placebo	Weighted mean difference (95% CI)	
Successful intercourse attempts (mean percentage)	57%	21%	34% (29 to 38)	
	Weighted event rates		RBI (CI)	NNT (CI)
	Sil	Placebo		
≥ 1 intercourse success	81%	45%	82% (68 to 99)	3 (3 to 3)
Improved erections	76%	25%	204% (165 to 249)	2 (2 to 2)

*Abbreviations defined in Glossary; RBI, NNT, and CI calculated from data in article using a random-effects model.

COMMENTARY

Since 1997, sildenafil has been prescribed to over 10 million people worldwide (1). The systematic review and meta-analysis by Fink and colleagues is one of several recent reviews and meta-analyses (2, 3) that show the effectiveness of sildenafil as first-line therapy for erectile dysfunction. The reported number needed to treat of 2 to 3 is consistent with other similar studies (3). Strengths of this review are its inclusion of unpublished data and the assessment of fixed-dose and flexible-dose regimens. The best relative benefit increase was shown in the crossover study included in the review. Higher doses of sildenafil were shown to have greater efficacy.

Although sildenafil was effective in all patient subgroups regardless of age, race, or comorbid illness (prostatectomy, spinal cord injury, diabetes, hypertension, psychogenic erectile dysfunction, ischemic heart disease, depression, or peripheral vascular disease), questions remain about the representativeness of men studied and duration of treatment effect. The average age of those enrolled was 55 years (plus or minus 10 y), 21% were Asian, 4% were black, and 70% had comorbid illnesses; the duration of treatment was 1 to 24 weeks. Physicians need more efficacy data about men who are black, > 75 years of age, have prolonged comorbid illness (e.g., diabetes mellitus > 20 y), and especially those who require long-term treatment. Clinical observation indicates that the effectiveness of sildenafil may wane over time.

Nevertheless, for a broad spectrum of men varying in age, race, and comorbid illness, sildenafil is clearly superior to placebo for short-term treatment of erectile dysfunction (1–3). Therefore, researchers should use sildenafil as the gold standard when assessing future treatments for this disorder, and physicians can be comfortable prescribing it to men not receiving nitrate therapy.

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References

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