

CASE REPORT

## Prolonged, longstanding, ultra-high-dose abuse of sildenafil

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ABSTRACT

We report a 40-year-old male who self-administered sildenafil for 10 years, in progressively increasing doses from 100 mg per occasion in the 1<sup>st</sup> year to 1300 mg per occasion in the 9<sup>th</sup>–10<sup>th</sup> years of (ab)use. The frequency of abuse was 2–3/week. The only adverse effect of concern that was reported was transient (up to about 12 h), self-limited blurring of vision in the last 2 years, especially in the last 2 months at the highest dose. The patient was otherwise normal. This report is unique because it describes what may be the highest dose of sildenafil reported in literature, abused across a protracted period of time. We discuss issues related to dose and safety of and tolerance to the drug.

**Key words:** Erectile dysfunction, phosphodiesterase type 5 inhibitors, sildenafil citrate

### INTRODUCTION

Erectile dysfunction (ED) is defined as the inability to achieve and sustain an erection of adequate rigidity for satisfactory sexual intercourse. Sildenafil citrate is a potent, competitive, phosphodiesterase type 5 isoenzyme inhibitor; it was the first in a class of effective oral treatments for ED of varying etiologies, including ED associated with drugs, diabetes, other general medical conditions, and spinal cord injury.

The safety and adverse effect (AE) profile of sildenafil is well documented.<sup>[1]</sup> Common AEs at therapeutic doses include headache, facial flushing, dyspepsia, dizziness, nasal congestion, abnormal vision, and palpitation. These AEs are generally mild, dose-related, transient, and self-limiting, and rarely warrant a change in therapy.

Sildenafil has been approved for use in ED in the maximum

dose of 100 mg per occasion; however, higher doses of up to 240 mg/day up to a year have also been safely used in patients with severe ED, ejaculatory delay, or pulmonary hypertension.<sup>[2-4]</sup>

We herein report a patient with prolonged abuse of high doses (1300 mg per occasion) of sildenafil with clinically significant but reversible AEs.

### CASE REPORT

L, a 40-year-old illiterate farmer, presented with a 12-year history of inability to sustain an erection for more than a minute. He described normal functioning in regular sexual activity in many premarital relationships from his late teenage years to age 28, at which point his ability to sustain an erection markedly and rapidly diminished across a period of a few months.

He married at age 30 and neither he nor his partner experienced sexual satisfaction despite normal levels

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of interest and drive. A psychiatrist whom he consulted prescribed sildenafil (100 mg) prior to intercourse. With the use of sildenafil, his ability to sustain an erection improved from 1 to 5 min. However, the benefits waned within 2 months, as a result of which he augmented the dose of sildenafil by approximately 100 mg per occasion per year.

By age 38, he was self-medicating with 8–9 tablets of sildenafil (100 mg, each) per occasion, and since then to the time of current consultation, he had been self-medicating at a dose of 1300 mg per occasion. At this level of dosing, he was able to sustain an erection for 5 min.

The reason for the present consultation was that, for the past 2 years and especially for the past 2 months, he had begun to experience blurring of vision starting within 20 min of sildenafil ingestion until about 8 a.m. the next day. These symptoms were present only on the days of sildenafil use. He was anxious about the possible risks associated with his high-dose sildenafil use; otherwise, there was nothing to suggest past or present medical or psychiatric illness. His use of alcohol and tobacco was small and infrequent.

Physical examination and a comprehensive laboratory workup were within normal limits. A complete clinical ophthalmological examination which included examination of fundus, visual acuity, and near vision identified no abnormalities, and no further ophthalmological study was considered indicated. No organic reason for the ED could be elicited to the extent that he was investigated in a routine hematological and metabolic work-up.

## DISCUSSION

This case is noteworthy for two reasons: First, the use of what might be the highest dose of sildenafil on record, and second, the use of ultra-high dosing for a decade, with 2 years at the highest dose of 1300 mg per occasion, at a frequency of 2–3 occasions per week. Importantly, there was no reported or identifiable adverse consequence except for transient and self-limited blurring of vision.

Many patients have used sildenafil daily for years with no apparent ill effects.<sup>[5]</sup> A single case report cannot testify to the safety of regular, ultra-high doses of sildenafil; this experience must be tempered by the data on the use of sildenafil in high doses and sildenafil overdose. In this context, doses of up to 240 mg/day for up to 12 weeks

have been used in patients with pulmonary hypertension; AEs observed include flushing, dyspepsia, and diarrhea. In this study, patients who completed 12 weeks of treatment could also enter a 1-year extension phase at 240 mg/day.<sup>[4]</sup> Single doses of 800 mg have been administered to normal volunteers, and all that was observed was an increased risk of the usual adverse events.<sup>[1]</sup> The highest first dose on record may be 2400 mg; the patient was a 33-year-old man, and the overdose resulted in annular scotoma, defective color vision, vascular retinal dilatation, visual field defect, and papilledema. Recovery was observed in all regards except for the visual field defect and the annular scotoma.<sup>[1]</sup>

Tolerance to sildenafil has been reported,<sup>[6]</sup> but so has efficacy for up to 4 years without requirement for dose increase.<sup>[7]</sup> It is possible that tolerance, if any, is due to progression in the organic pathology responsible for the ED. Our patient was only partially investigated, and so we do not know whether there was an identifiable pathology responsible for his ED, and whether there was progression in this pathology, necessitating higher doses for maintained efficacy.

On a concluding note, it is an indictment of the dispensing system that allows patients such easy access to prescription drugs over such a long period.

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## Conflicts of interest

There are no conflicts of interest.

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