EDITORIAL COMMENT

Penetration and maintenance of erection with vardenafil: a time-from-dosing analysis

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This report highlights many of the strengths and weaknesses of current erectile dysfunction (ED) clinical research. While the authors report clear messages concerning the safety and efficacy of vardenafil, the population studied is a select one. As is the case in most contemporary ED studies, sildenafil responders are recruited while sildenafil non-responders are excluded. In this manuscript more than 50% are previous sildenafil responders. While the authors cite another analysis of this data set showing comparable results between the sidlenafil naive men and those who are responders, I would suggest this exclusion criteria may yield an enriched population of responders.

The search for an oral agent which is rapidly absorbed, has a fast onset of action, and displays an extended period of responsiveness, is actively ongoing by patients and researchers world-wide. In this report the utility of vardenafil 8-12 hours post-dose is highlighted. Clearly, the small numbers of attempts and the high placebo response rates during this period, limited what the authors could claim about extended duration. Their use of SEP 2, the ability to penetrate the vagina is a threshold that is easier to achieve than SEP 3 - maintenance of erection until completion of sexual contact. I have difficulty interpreting whether high SEP 2 rates correspond to satisfaction among my patients, who generally want the confidence to maintain their erections until they reach an orgasm (SEP 3).

As a result, should we tell our patients to attempt intercourse as early as 15 minutes or as late as 8-12 hours post-dose with vardenafil? Based on this report, many of my patients would likely not succeed and may return unhappy with their failure. The data for 30-120 minutes shows high success rates for SEP2 and SEP3. On the other hand, the knowledge that vardenafil can provide an early and extended period of sexual enhancement for a significant percentage of men may be important new information for those seeking more spontaneity.

This retrospective review fails to answer the key question about how long post-dose vardenafil remains trully effective. It does however, make the point that 2 - half-lives after ingestion of a PDE5i may result in an adequate degree of enzyme inhibition (25% of maximum) to afford some men a wider window of opportunity; a point worth passing on to all of our patients.

Respectfully submitted

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Reply by authors: The editorial comment is right regarding strengths and weaknesses of current erectile dysfunction (ED) clinical research. This is true for most articles in the field, including this one. The editorial comment accurately mentions the quest of the ideal agent for ED, with a fast onset and a prolonged period of responsiveness. Available agents are unfortunately labeled as either fast/short acting or long acting, while in reality, for many patients, the distinction is not so sharp. Both SEP 2 and SEP 3 were used in this retrospective analysis, and the intent of the analysis was not to specifically assess the exact duration of action of vardenafil. Although most sexual attempts occurred early after dosing in both study groups, this analysis clearly illustrates that, in comparison to placebo, vardenafil can provide an early (15 minutes or less) and extended period of sexual enhancement (through 8-12 hours for SEP 3) for a significant percentage of men and the editor appropriately mentions that this may be important new information for those seeking more spontaneity.

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