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Treatment for Erectile Dysfunction Based on Patient-Reported Outcomes

To Every Man the PDE5 Inhibitor that He Finds Superior

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Abstract

Erectile dysfunction (ED) is a common medical condition linked both to aging and to many medical conditions such as diabetes mellitus and cardiovascular disease.

Although a common condition, treatment for ED has in the past been conducted by a few specialists, mostly urologists and sex therapists. The revolutionary introduction of oral therapy, and the massive amount of research into sexual dysfunction that followed, has led to paradigm shift in the treatment of ED. This is no longer something done by a few for a few; it involves all disciplines of medicine and more patients are being treated by a greater number of physicians.

Several medications administered by different routes are available for treating ED but oral pharmacotherapy represents the first-line option. Phosphodiesterase (PDE) type 5 inhibitors are the most widely prescribed oral agents and they have a satisfactory efficacy-safety profile in patients of all categories. An alternative for men who do not respond to PDE5 inhibitors is intracavernosal injection therapy with alprostadil, a prostaglandin analogue. Other alternatives include sublingual apomorphine and intraurethral alprostadil. Both agents have a less satisfactory efficacy profile than PDE5 inhibitors and a low compliance rate.

The aim of ED treatment is to restore an erection satisfactory for the sexual needs of the patient. Thus, the patient-reported outcome is the gold standard in efficacy evaluation.

There are now three PDE inhibitors available, all with satisfactory efficacy-safety profiles, but with different pharmacokinetic properties. The availability of three different agents has initiated studies aiming to evaluate them regarding patient preference. However, the results are rather conflicting with some studies suggesting that tadalafil has the best patient preference, while others fail to demonstrate a clinically significant difference between the three agents. However, there is a tendency for younger men to choose tadalafil because it gives them a broader window of opportunity, while older men tend to prefer vardenafil or sildenafil. These data could be used when making a decision on which PDE5 inhibitor to prescribe, although another option is to let the patient try all three available agents and make his own choice.

Erectile dysfunction (ED) is defined as the inability to achieve and/or maintain an erection adequate for sexual intercourse. It is an age-related, progressive condition affecting, to some degree, >50% of men aged 40–70 years.[1]

It is now common knowledge that ED can be successfully treated. The first step in the treatment ladder is a phosphodiesterase (PDE) type 5 inhibitor given orally, while the second step is intracavernosal prostaglandin injections.[2] There are other options such as apomorphine administered sublingually and intraurethral instillation of synthetic prostaglandin analogues, but they are less effective and have a low compliance rate.[3] The introduction of effective medications has initiated intensive activity around all aspects of ED. This includes studies on the efficacy of the treatment modalities available, especially the PDE5 inhibitors.[2]

The outcome of a treatment can be measured by laboratory tests and device measurements, or on clinician-reported outcomes or patient-reported outcomes (PROs).[4] While objective endpoints in clinical trials are imperative in gaining approval for drug registration, for ED it is rather obvious that the PRO of the direct therapeutic effect is also important.[5] ED and its treatment are a unique situation in that the patient and his partner are the only ones who can evaluate all aspects of the treatment and, hence, PROs should be the gold standard. The complexity and great variety of the human sex life make it almost impossible for a physician, even with the most thorough work-up and history taken, to be sure that they will select the optimal therapy for the couple. Only the patient and his partner are able to judge this.[6] Comparative studies measuring quality of life could also be valuable.

Notwithstanding the widespread use and notoriety of sildenafil, many men with ED either do not come forward for treatment or discontinue therapy after a short period of time.[7,8] This situation is despite the fact that treatment seeking is strongly associated with disease severity.[7]

The discontinuation rates for sildenafil are high and range from 29% at 5 months in responders to as high as 72% after 1 year.[9] Despite the availability of PDE5 inhibitors, the nearly 'ideal' remedy, many men with ED do not need or want them. Many patients want to try a new medication but discontinue usage because of the continuous financial burden to them.

The aim of this review is to give a clinically oriented overview of patient-reported outcomes in ED treatment with a focus on PDE5 inhibitors. To keep it up-to-date, the literature list includes several recent conference abstracts.

1. Drug Therapy in Erectile Dysfunction

1.1 Phosphodiesterase (PDE) Type 5 Inhibitors

Penile erection is a haemodynamic event regulated by relaxation of arteriolar and trabecular smooth muscle cells in the corpora cavernosa, which is mediated via the nitric oxide (NO)-cyclic guanosine monophosphate (cGMP) pathway.[10]

Following sexual stimulation, neuronal impulses cause the release of NO into the corpora cavernosa. As a result of this, the penile blood flow increases and sinusoidal spaces expand, preventing venous outflow and producing an erection. The PDE inhibitors used for ED treatment are selective competitive inhibitors of PDE5, an enzyme that breaks down cGMP, the second messenger of NO. By inhibiting cGMP breakdown, PDE5 inhibitors enhance the vasodilatory effect of NO and restore the ability to achieve an erection in patients with ED. Thus, PDE5 inhibitors are only effective with simultaneous sexual stimulation.[10]

There are currently three different inhibitors available: sildenafil,[11,12] vardenafil[13] and tadalafil[14,15] (table I).

As competitive inhibitors of PDE5, the chemical structures of the substances are very similar to that of cGMP. Sildenafil and vardenafil have a similar structure.[16] However, tadalafil differs markedly from sildenafil and vardenafil in terms of its molecular structure, which is also reflected in pharmacokinetic differences (table I).

Sildenafil was the first PDE5 inhibitor available and a large experience regarding its use has been gathered. The concomitant use of nitrates is the one

Table I. Differentiating properties for the available phosphodiesterase (PDE) inhibitors[13,15,16]

PDE5 inhibitor	Time to onset (min)	Effect duration (h)	Adverse effects
Sildenafil	30–60	4–6	Headache, flushing, dyspepsia
Vardenafil	10–25	3–4	Headache, flushing, rhinitis
Tadalafil	15	18–36	Headache, dyspepsia, back pain

contraindication with sildenafil as for all PDE5 inhibitors, as this may cause sudden hypotension.[2] Caution should also be exercised regarding the coadministration of α-adrenoceptor antagonists (α-blockers). While adverse events are mostly minor and transient (table I), the withdrawal rate is significant.[8,9] There are several causes for this, ranging from those having been cured by the drug to patients whose sexual interest has declined with time and age. Discontinuation as a result of treatment-related adverse events is uncommon.[8,9]

Sildenafil is able to restore erection in all types of ED. In clinical practice studies, the success rate is around two-thirds.[12] Not surprisingly, treatment satisfaction correlates with ED severity and aetiology, with the best success rate if the cause is psychogenic or vasculogenic.[9,12] Sildenafil is less effective in ED secondary to diabetes mellitus and radical prostatectomy.[12]

The efficacy of the more recently introduced PDE5 inhibitors is virtually the same as for sildenafil.[16] However, there are differences in time to onset, duration of the effect and, to a lesser degree, in adverse effect pattern (table I).

The potency and selectivity of vardenafil are somewhat superior to sildenafil, at least in an animal model,[17] but is not really known if this translates into clinically significant benefits for the ED patient. As for sildenafil, absorption of vardenafil is impaired by fatty food.[16] In a meta-analysis, vardenafil increased the erectile function domain of the International Index of Erectile Function (IIEF) by 6.2 points.[18] This is very similar to the increase of 6.5 and 8.6 points for the two doses (10 and 20mg, respectively) of tadalafil tested.[15]

The longer erectogenic potential (table I) of tadalafil and the lack of interaction with food in the absorption of the drug are advantages that may allow for more spontaneous sexual activities.[2,16]

The time to onset of function is also shorter for tadalafil and vardenafil than for sildenafil (table I), which could be considered an advantage for many patients. However, reliability, tolerability and safety are more important than both rapid onset and long duration.[19]

1.2 Other Erectogenic Agents

Intracavernosal prostaglandin injection is more effective than the PDE5 inhibitors in the treatment of ED.[2] However, because of the invasive nature of the method, intracavernosal injection is a second-line treatment.[2] If a patient obtains a satisfactory erection with a PDE5 inhibitor there is no reason for him to consider intracavernosal injections. Thus, studies on patient preference comparing intracavernous injections with PDE5 inhibitors are of little interest for clinical practice. Patients who do not respond to PDE inhibitors, however, frequently receive salvage treatment in the form of intracavernosal therapy.[20]

In contrast, intracavernous injections are preferred and are more efficacious than intraurethral alprostadil.[21] Therefore, there is little place for the intraurethral instillations, a method associated with a significant number of local complications.

Apomorphine acts centrally and nausea is a frequently occurring adverse effect. Although sublingual apomorphine is significantly more effective than placebo in inducing erections firm enough for penetration and increase the intercourse rate,[22] the erectogenic effect is weak and sildenafil is much more effective.[23]Apomorphine is said to be an alternative for men in whom PDE5 inhibitors are contraindicated because of severe cardiac disease and/or the use of nitrates;[2] however, the weak erectogenic effect and nausea have made apomorphine a seldom-used alternative.

2. Patient-Reported Outcomes

2.1 Patient Preference

The simplest way to establish patient preference in ED treatment is to let the patient try the available agents and state which one he prefers. This appears to be a robust method but there are biases. For example, price may pay a role if the patient is to pay for the treatment himself. Also, the order in which the agents are tested may influence the preference.[5]

Another simple method is a patient's log of erectile activity in which the number of successful erections are registered.[5]

A preference study on the three PDE5 inhibitors would ideally show more than a small but statistically significant difference between the preferences. So far, no study has shown an overwhelming difference between the available drugs.[5,24]

2.1.1 Scales as a Measure of Patient Preference

The IIEF examines five domains, including erectile function. It is used in an abbreviated form, the IIEF-5, to evaluate erectile ability exclusively. The IIEF-5 scale is a well validated and much used scale for evaluating erectile function.[25] The score obtained is an indirect measure of patient preference in which a high score indicates a good erection; however, it does not reflect how satisfied the patient is with the situation. The PDE5 inhibitors are indeed effective: tadalafil increased the score from 15.3 to 25.1 compared with an increase from 16.0 to only 17.4 in the placebo group.[14]

The Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) scale was developed to obtain information on patient satisfaction. EDITS evaluates both patient and partner satisfaction with ED treatment.[26]

2.1.2 Prescription Renewal

Prescription renewal (refilling) has been used as a measure of patient preference.[27] Discontinuation of an agent is then evaluated from the number of patients who return to the pharmacy with a new prescription of the drug in question. This is a method that reflects the 'real-life setting' more than controlled clinical trials. One such study revealed that 45% of all patients (n = 317) discontinued sildenafil treatment after a median follow-up of 18 months.[27] Age >60 years and diabetes were associated with an increased likelihood of discontinuing sildenafil. No such studies evaluating tadalafil and vardenafil have been presented.

2.2 Quality of Life, Self Esteem and Erectile Dysfunction

It is a truism to say that ED can profoundly impair quality of life and that the restoration of a satisfactory erection is linked to an improvement in life quality.[28] Two-thirds of the men in an online survey thus felt that ED reduced their self-esteem; nearly one-third said that their relationship has been affected.[29] The launch of sildenafil generated high, sometimes unrealistic, expectations. Where the treatment was successful, a renewed self-confidence occurred,[30] particularly in existing relationships or in forging new ones, but where it did not work the distress could be severe.[29]

Still, far from all men with ED seek medical attention.[7] Many men also decline therapy when offered it, and less then half of those who try a form of treatment are long-time users.[7] There are several reasons behind this, including the cost of the drug, return of natural erections and loss of a partner.[5,7] Another common reason is the declining interest in sexual activities linked to aging; that is, the man has ED but is not so bothered by it, and nor is his partner, that he cares to seek medical attention, even when he knows that there are effective treatments available.

2.3 Goal-Directed Therapy

One approach used to evaluate men with ED is to undertake an extensive assessment using a multidisciplinary approach. However, the underlying aetiology rarely affects the ultimate treatment choice for the patient and, according to this concept, it is reasonable to limit diagnostic evaluations to tests that may influence management.

Another more direct approach is to let the patient try all three available PDE5 inhibitors and make his own choice.[8] This method gives a high overall

efficacy (91%). Another finding from this study was that one-fifth of men wanted both a short- and a long-acting agent.

2.4 Studies Comparing the PDE5 Inhibitors

Currently, an important issue in the treatment of ED is which PDE5 inhibitor to recommend.[5] A series of recently performed studies have addressed this issue by examining patient-related outcomes. Five separate, pharmaceutical industry-sponsored studies have examined patient preference between sildenafil and tadalafil, with three being open-label switch studies in men already taking sildenafil.[31-35]

In an international multicentre study with a double-blind crossover design, 219 men were randomised to either sildenafil 50mg or tadalafil 20mg for 12 weeks.[31] In the drug preference assessment 132 of 181 (73%) evaluable patients chose to receive tadalafil ($p < 0.001$) during the extension period. However, this study has been rather heavily criticised on the basis of a defect in the study design limiting its applicability to the general population. For example, the study compared tadalafil 20mg (the maximal dose) with variable doses of sildenafil, and only 35% of patients receiving sildenafil 50mg were given the opportunity to receive 100mg if needed. In an earlier randomised, crossover, double-blind multicentre trial comparing tadalafil 20mg with sildenafil 50mg for 4 weeks, two-thirds of 190 evaluable patients preferred tadalafil (as measured by patient statement).[32] The dose used was the starting dose for each agent. Thus, the study was not designed to be a comparison of maintenance treatment.

In an open-label multicentre study, men who were taking sildenafil (at the currently recommended dosage of 25–100mg) tested tadalafil 20mg for 8 weeks.[33] Of the 2453 men, 82% preferred tadalafil (measured by a simple question). The main factors influencing this choice were an improvement in timing concerns and in sexual self-confidence. Patients who took >2.5 sildenafil doses per week or high doses of sildenafil had a greater likelihood of remaining on sildenafil. Another open-label multicentre study, evaluated 2762 men who switched from sildenafil 25–100mg to tadalafil 20mg for 8 weeks regarding their preference and with relationship scales.[34] Of the 2762 men enrolled, 83% preferred tadalafil. The reasons for their choice were fewer timing concerns, greater spontaneity and better sexual self-concern, measured by a Psychological And Interpersonal Relationship Scale. In an earlier, short-term, open-label study, 147 patients who were taking sildenafil 25, 50 or 100mg switched to tadalafil 20mg. Ninety percent of patients preferred tadalafil to sildenafil.[35]

In addition to these five studies, there are also a number of smaller industry independent studies of patient preference in ED treatment. Patient preference was measured by simply asking the patients which medication they preferred at the end of the study.

In one study from Korea, patients with ED tested all three drugs in equivalent doses on at least three occasions. Of the 59 men included, 58% ($n = 34$) preferred sildenafil, mainly because of a more satisfactory erection.[36] In a German study,[37] the enrolled men ($n = 72$) underwent a 12-week test period of the three different PDE5 inhibitors (4 weeks with each drug; study design not specified). The investigators concluded that all three agents were equally effective with no statistical differences regarding efficacy (measured by patient preference). However, in line with the other studies,[36,38] they noted that younger men tended to prefer tadalafil because of its longer efficacy and older men preferred vardenafil.

A Swedish unsponsored clinical study[8] evaluated the preference of men who were given the opportunity to test all three agents. Fifty percent of the 186 men completing the study preferred tadalafil. However, among the one-third of men who were naive to ED treatment there was no difference in patient preference between the drugs. A further study, which was not supported by the pharmaceutical industry, also examined patient outcomes in PDE5-naive ED patients; 418 patients tested each PDE5 inhibitor at least four times. An IIEF-5 score was obtained as well as patient preference. There was no difference in patient preference or in the drug-induced IIEF score increase between the three

drugs.[38] However, there were marked subgroup differences. Young men with mild dysfunction preferred tadalafil, while older men, who often had more severe ED, preferred sildenafil or vardenafil.

3. Discussion

The use of PDE5 inhibitors has markedly improved the treatment of diverse populations of men with ED of broad-spectrum aetiology.[13,24] The three agents now available have shown significant clinical efficacy, safety and tolerability in numerous clinical trials.

That the pharmaceutical companies have sponsored so many of the PDE5 preference studies is a problem. Even if a study is conducted according to Good Clinical Practice guidelines and sponsored by an 'unrestricted' grant, the company can be involved in the research question selection as well as evaluation and presentation of the results. Thus, in studies supported by industry the results of patient preference outcomes tended to differ from those emerging from independent single-centre studies. The design and results of most published studies are rather confusing for both patient and physician. Because of the lack of an appropriate consensus that is based on head-to-head comparisons, the role of the physician is considered important. Dose administration instructions, explanation of the mode of action and setting realistic expectations for the patient (and the couple) can make a large difference in patient satisfaction. However, it is difficult for the physician to be able to judge which is the best PDE5 inhibitor for the specific man (or couple).[6] A pragmatic way to eliminate this dilemma is to let the patient test all of them in order to make his own choice.[8]

Comparative studies measuring patient-related outcomes other than patient preference, i.e. quality of life and self-esteem, would be valuable in the assessment of optimal ED treatment, but there are currently none published. However, the recent development and validation of a self-esteem questionnaire should make it possible in the future.[30]

4. Conclusions

Of the many remedies for ED available today, orally administered PDE5 inhibitors are the most widely prescribed agents. The success rate of PDE5 inhibitors in clinical practice is around two-thirds. The three currently available inhibitors, sildenafil, vardenafil and tadalafil, all have satisfactory efficacy-safety profiles. However, the results of the patient preference studies performed are rather conflicting and, therefore, provide limited guidance. One option is to let the patient test all three agents, and select the optimal treatment for him and his partner.

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