INVESTIGATION IN PATIENTS WITH ERECTILE DEFICIENCY UNDER TADALAFIL TREATMENT, USING PAIRS (Psychological and Interpersonal Relationship Scales) OUESTIONNAIRE

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Introduction

Tadalafil, a drug used in treating Erectile Deficiency (ED), is a PDE5 inhibitor even though much more specific for treating this isoform compared to the others. The efficacy and safety of this well-known drug has been widely proven through experiments.

Our study had the aim of observing patients with ED of different severity and etiology, who were prescribed Tadalafil treatment (10 or 20 mg on demand), in order to understand the impact in terms of "acceptance" regarding the partner relations and to establish the extent to which these relations had been influenced by the treatment.

Although oral treatments of the erectile deficiency have become usual in daily clinical practice today, attitudes of little acceptance or even distrust persist towards a supposed medicalisation of an aspect of life such as sexual activity that should be as natural and spontaneous as possible in the common view: Indeed, patients dislike the feeling that they have to plan sexual intercourse according to the duration of the drug's action or that they have to wait until the drug starts working each time they decide to begin sexual activity.

This attitude applies to the patient himself but resistance is also put up by his partner for similar reasons, as she might see the drug as a solution on one hand but on the other, although wrongly, she might feel the importance of her role diminished ("the erection is produced by the drug, not by me").

Materials and Methods

All the patients suffering from ED who were observed from April 1st to September 15th, 2003 were supplied with the International Index of Erectile Function (IIEF) (questions 1-5, 15 – Control of Erection) after an initial treatment with Tadalafil (8 tablets). The first 250 patients who underwent examination after the eighth administration were invited to fill in a copy of the Italian version of Psychological and Interpersonal Relationship Scales (PAIRS) Questionnaire (questionnaire on partner relations from a psychological viewpoint) (*Swindle et al*, 2004).

The age of these 250 patients ranged between 27 and 60 years (mean 42.2 years). The IIEF score ranged between 10 (severe ED) and 24 (mild ED) with a mean of 16.2 (moderate ED).

According to the IIEF score, 64 patients suffered from severe ED, 125 moderate ED and 61 patients mild ED.

Ninety-seven patients were treated with 10 mg Tadalafil, whereas the other 153 patients used a dosage of 20 mg (at least for the last six administrations).

One hundred and twenty-one patients had sexual intercourse between 2 and 12 hours after taking the drug, 67 patients between 12 and 24 hours and 62 patients even beyond 24 hours.

All the patients were invited to specify their position with respect to the 29 statements given in the PAIRS Questionnaire, declaring whether they: "strongly disagree", "disagree", "agree" or "fully agree".

Results

The patients' answers to the 29 statements in PAIRS were as follows (Tab.1):

| Statement | A | В | С | D |
|-----------|-----|-----|-----|-----|
| 1 | 23 | 138 | 51 | 38 |
| 2 | 27 | 113 | 98 | 12 |
| 3 | 22 | 65 | 91 | 72 |
| 4 | 28 | 62 | 87 | 73 |
| 5 | 48 | 98 | 40 | 64 |
| 6 | 54 | 89 | 97 | 10 |
| 7 | 117 | 78 | 47 | 8 |
| 8 | 102 | 58 | 60 | 30 |
| 9 | 94 | 44 | 110 | 2 |
| 10 | 6 | 102 | 87 | 55 |
| 11 | 71 | 63 | 103 | 13 |
| 12 | 9 | 58 | 79 | 104 |
| 13 | 26 | 48 | 85 | 91 |
| 14 | 55 | 65 | 108 | 22 |
| 15 | 46 | 45 | 102 | 57 |
| 16 | 10 | 24 | 138 | 78 |
| 17 | 2 | 47 | 124 | 77 |
| 18 | 61 | 98 | 67 | 24 |
| 19 | 21 | 46 | 89 | 94 |
| 20 | 115 | 63 | 22 | 50 |
| 21 | 9 | 63 | 114 | 64 |
| 22 | 22 | 36 | 102 | 90 |
| 23 | 8 | 51 | 148 | 43 |
| 24 | 91 | 100 | 49 | 10 |
| 25 | 43 | 128 | 55 | 24 |
| 26 | 76 | 113 | 50 | 11 |
| 27 | 9 | 67 | 125 | 49 |
| 28 | 7 | 80 | 65 | 98 |
| 29 | 9 | 71 | 111 | 59 |

A = No of patients strongly disagreed B = No of patients disagreed C = No of patients agreed D = No of patients fully agreed

- 1- "When we meet, I feel that we do things in a hurry if we have planned to have sexual intercourse later"
- 2- "I am aware that the drug might not work if I wait too long before having sexual intercourse after taking the drug"
- 3- "We manage to relax and not to worry when we meet"
- 4- "Me and my partner had an argument after I had taken the drug"
- 5- "I am able to perform like before"
- 6- "When I have taken the drug I want to have sexual intercourse as soon as the drug begins to work"
- 7- "Meetings seem to be scheduled for having sexual intercourse at pre-established times"
- 8- "My partner sometimes feels constrained to have sexual intercourse with me"
- 9- "Sometimes I realize that taking the tablet had been a mistake"
- 10- "I am very sure of my sexual performance"
- 11- "Sometimes we argue whether to have sexual intercourse after I have taken the tablet"
- 12- "We have much time for caressing and feeling close before we have sexual intercourse"
- 13- "We are able to feel at our ease without worrying about time"
- 14- "Sometimes I have wasted a tablet because we did not try to have sexual intercourse"
- 15- "I am very happy about my sexual life"
- 16- "When we go out together, we feel free to change our plans at any moment"
- 17- "Before having sexual intercourse, we are able to be together spontaneously"
- 18- "After taking my tablet, I sometimes realise that I have misinterpreted my partner's interest in having sexual intercourse"
- 19- "We can talk freely without feeling in a hurry when we are alone before having sexual intercourse"
- 20- "Sometimes I spoil the atmosphere because I have to mind time"
- 21- "We are able to feel relaxed when we go out together"
- 22- "I feel I can "let go" when I am alone with my partner before having sexual intercourse"
- 23- "I am sure I shall have an erection if there is the right atmosphere"
- 24- "I get into a rush when I think that we shall have intercourse later"
- 25- "I worry about the fact that the drug's effect may fade before we have had sexual intercourse"
- 26- "I had to try to win my partner over to the idea of having intercourse after taking my tablet"
- 27- "I am sure I can have intercourse in a spontaneous and enjoyable way"
- 28- "We have time to stay together in a romantic and relaxed way when it is probable that we shall have sexual intercourse later"
- 29- "It is very easy to have satisfactory sexual intercourse"

Discussion

The anamnestic data collected showed that 44 patients have had sexual intercourse 8 times when using the drug at an optimal dosage, 21 patients have had intercourse 7 times, 123 patients have had only 6 times, 51 patients not more than 5 times and 11 patients not more than 4 times.

The patients' answers revealed that the majority of them

- a) are satisfied with the treatment even though they had experienced it for a short time and their erections were reinforced by it (Statement 23: 76.4% agreed; Statement 29: 68.0% agreed; Statement 15: 63.6% agreed [to be considered however the particular wording of this statement: "I am *very* happy about my sexual life"]);
- b) do not feel influenced by the drug intake during the activities of the couple (go for a walk, go out for dinner etc.) (Statement 3: 65.2% agreed; Statement 19: 73.2% agreed; Statement 21: 76.8% agreed; Statement 28: 65.2% agreed);
- c) feel also that they have all the time necessary for "caressing and feeling close" before having sexual intercourse (Statement 12: 73.2% agreed; Statement 13: 70.4% agreed; Statement 17: 80.4% agreed; Statement 22: 76.8% agreed);
- d) emphasize that, thanks to Tadalafil treatment, they have reached the important goals of both a spontaneous attitude (Statement 27: 69.6% agreed, confirmed by the disagreeing answers to Statement 6 [57.2%], to Statement 7 [78.0%] and to Statement 8 [64.0%]) and the possibility to change program as they like before having sexual intercourse (Statement 16: 86.4% agreed);
- e) report that they do not worry about time (confirmed by the disagreeing answers to Statement 2 [56%], to Statement 24 [76.4], to Statement 25 [68.4]), thus avoiding tensions that might "spoil the atmosphere" (Statement 20: 71.2% agreed).

As regards the female partners, it appears that sometimes they feel constrained to have sexual intercourse when their partner has taken the drug (Statement 26: 24.4% agreed; this result is possibly confirmed by the agreeing answers to other statements that intimate that initially, no agreement on sexual intention was present between the partners, i.e. Statement 11 [46.4% agreed], Statement 14 [52.0% agreed] and Statement 18 [36.4% agreed], or that partners have had an argument (Statement 4: 64% agreed).

This result should be reviewed on a long term: We must not forget that the questionnaire has been filled in after not more than 8 Tadalafil tablets administered on demand. This means that the couples had sexual intercourse not more than 4 to 8 times facilitated by the drug at an optimal dosage (see above). It is probable, although it has to be ascertained, that the systematic long-term use of the drug may make the couple relax allowing the female partner to face the sexual experience more spontaneously and perceive again that her seductiveness plays an important role in the sexual relation.

Apparently discordant data were obtained for Statement 5 (41.6% agreed) and Statement 10. Statement 5 ("I am able to perform like before") is clearly ambiguous: The answering patient probably does not forget that, differently from "before", he is taking a drug to have sexual intercourse. Only 56.8% of the patients agreed with Statement 10; but the term "very" ("I am very sure of my sexual performance") may be too much for patients who have just begun the experience of an effective treatment of ED.

Finally, a quite high number of patients (44.8%) state (Statement 9): "Sometimes I realize that taking the tablet had been a mistake": On the basis of our experience, this may be explained by the fact that nearly all the patients who suffered from ED only a few tablets ago, so that they went so far as to consult a specialist, usually believe that each tablet swallowed must correspond with sexual intercourse (administration was on demand).

Conclusions

Approximately three quarters of all the patients think that, thanks to Tadalafil on demand, they are able to have sexual intercourse in a spontaneous and enjoyable way, obtaining satisfactory intercourse without feeling that they have to follow a time schedule for their sexual activity.

This positive result is definitely obtained thanks to the drug's long half-life (17 hours), including the possibility that effective drug concentrations are still present in the blood even after more than 24 hours from intake.

This feature is highly appreciated by the patients as it allows the objective but also conceptual separation of drug intake and sexual activity thus providing freedom of planning. This aspect considerably contributes to the mitigation or even elimination of the apparent mechanization existing between drug intake und its effect (i.e. the erection) that in any case can only be obtained after adequate sexual stimulation by the partner.

REFERENCES

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