Short and Long-Term Follow up Results of Daily 5 Mg Tadalafil as a Treatment for Erectile Dysfunction and Premature Ejaculation

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Abstract

Objective: To evaluate effectiveness and safety of a 5mg tadalafil daily treatment for men with erectile dysfunction (ED) and premature ejaculation (PE) and assessment of long-term follow up by persistence of improvement 2 years after stoppage of tadalafil.

Materials and Methods: The study included 160 patients diagnosed with erectile dysfunction from April 2018 to June 2020. All were evaluated using the international index of erectile function questionnaire-5 (IIEF-5) to evaluate ED and intravaginal ejaculatory latency time (IELT) for PE. Patients subdivided into two equal groups. I included 80 patients treated with tadalafil 5 mg daily for 3 months, and group II included 80 patients treated with a placebo for same period. After 3 months treatment and 2 years later after stoppage of tadalafil, all patients were assessed for ED and PE using the same questionnaires.

Results: The mean IELT and IIEF pretreatment were 37 ± 11.24 s and 13.2 ± 4.2 respectively for group I, while in group II was 35.98 ± 10.8 s and 13.12 ± 4.11 , respectively. After 3 months of treatment, the mean value of IELT in group I showed a highly significant improvement from 37 ± 11.24 sec to 120.5 ± 47.37 sec (p -value < 0.001), but for group II, the mean values of IELT showed no significant improvement from baseline 35.98 ± 10.8 to endpoint 39.43 ± 13.6 (p -value > 0.05). As regarding the IIEF, there was a highly significant improvement from baseline 13.2 ± 4.2 to endpoint 20.45 ± 4.5 in group I (p -value < 0.001) while there was no significant difference in group II from baseline 13.12 ± 4.11 to endpoint 15 ± 4.84 (p -value > 0.05). 2 years later after stoppage of tadalafil, 75 patients from group I complete follow up and there was significant improvement in IELT and IIEF from base line (37 ± 11.24) (13.2 ± 4.2) to endpoint (98 ± 18.3) (19.1 ± 2.3) respectively but less than the results after 3 months treatment.

Conclusion

Daily Tadalafil 5 mg was effective, tolerable, and safe treatment for patients suffering from ED and PE. Long-term follow up after 2 years declared persistence of significant improvement.

Introduction

Erectile dysfunction (ED) and premature ejaculation (PE) are the most common sexual dysfunctions where a prevalence of about 30 % and 20 %, respectively^{1,2}.

Erectile dysfunction (ED) is a failure to accomplish and maintain an adequate erection to reach satisfaction with sexual intercourse. Premature ejaculation is defined by International Statistical Classification of Diseases and Related Health problems as the inability to control ejaculation which sufficiently enough to enjoy both partners during sexual intercourse³.

Sexual dysfunction including ejaculatory and orgasmic disorders, ejaculatory disorders including PE, and retarded ejaculation (RE), but orgasmic disorders including anorgasmia and hyporgasmia. According to

the predictor factors, the PE is classified into primary or lifelong and secondary or acquired. Organic factors are the commonest predictors for acquired PE like and endocrinal disorder^{4, 5, 6}.

PE is coexisting with ED in 30 % of patients, especially secondary PE. International index of erectile function Questionnaire-5 (IIEF-5) and intravaginal ejaculation latency time is used to evaluate the erectile dysfunction and premature ejaculation, respectively. IELT has higher sensitivity and specificity for the evaluation of PE⁷.

There are many modalities for PE treatment, the most commonly used are behavioral and pharmacological therapy, but behavioral therapy is inefficient for many couples.

Although many drugs are used for PE, serotonin reuptake inhibitors (SSRIs) are the most common drugs used in PE. Other medications like topical anesthesia or opioid agonist like tramadol are less commonly used⁸.

Phosphodiesterase-5 inhibitors (PDE5i), which are commonly used in the treatment of ED, have been recently experienced in some studies to treat **PE**^{9,10,11}.

Sildenafil and tadalafil are the most frequently used PDE5i; there are imperceivable data about the difference between sildenafil and tadalafil.

Tadalafil with once-daily (OAD) and on-demand PRN dose regimens is sufficient for treating ED. Other studies reported that the tadalafil OAD dose regimen is better, and more sexual satisfaction occurred than PRN^{12, 13}.

Our study evaluated the efficacy and safety of daily tadalafil 5 mg in patients suffering from ED and PE versus placebo and also the improvement after stoppage of tadalafil for long time.

Patients And Methods

A prospective, single-blind, randomized study comparing the safety and efficacy of tadalafil 5 mg continuous daily dosing for three months compared with placebo for treatment of erectile dysfunction with premature ejaculation. And assessment of persistence of improvement after 2 years of tadalafil stoppage on 75 patients on tadalafil group as 5 patients were lost during follow up period.

This study was conducted on 160 patients coming to the urology outpatient clinic, from April 2018 to June 2019, suffering from erectile dysfunction and life long premature ejaculation for the last six months of the continuous marriage relation. Patients with neurogenic disorder, parkinsonism, diabetes mellitus, active urinary tract infection, chronic prostatitis, chronic renal failure, and with medications affecting erectile function were excluded from the study.

Written informed consent was taken from all patients enrolled in this study, which was ethically approved by the local ethical committee.

The sample size was calculated using the EPI info 2000 statistical package. The null hypothesis of the study will be that tadalafil had no treatment effect relative to placebo. To reject the null hypothesis, statistical significance at $p < 0.05$ will be required on all two co-primary endpoints (the IIEF, EF). Considering a 20% dropout rate, a sample size of 160 patients (placebo, 80 and tadalafil, 80) was calculated to give 90% power to detect a significant treatment effect. Patients were divided into two equal groups using the closed envelop method, the group I included 80 patients have treated with a daily tadalafil 5 mg oral tablet for three months. Group II included 80 patients who were treated with a placebo for the same period. Tadalafil group were followed up for 2 years after stoppage of tadalafil, but 5 patients were lost in follow up period and 75 patients were assessed at the end of 2 years.

Full medical and sexual history was taken with the history of current medications, a complete physical and genital examination was performed, and all patients were evaluated using IIEF-5 to evaluate ED and IELT for PE before and after treatment and at the end of 2 years follow up.

Statistical analysis

The collected data were revised, organized, tabulated, and statistically analyzed using statistical package for social sciences (SPSS) version 25.0 for mac software (IBM SPSS corp., Armonk,N.Y.,USA). Data are presented as the Mean $\pm$ standard deviation (SD); Continuous variables in comparable groups were compared by the Student t-test (two-taileds.In intention-to-treat (ITT) analysis, all randomized patients were included in their original group irrespective of their compliance with treatment or lost to follow-up. Subjects who lost the follow- up were considered as a failure to treat. The level of significance was accepted if the P-value < 0.05 .

Results

Both groups were comparable regarding the mean age, weight (Kg), and height (cm), 36.3 ± 11.6 , 78.9 ± 8.4 , and 171.3 ± 14.6 , for the group I, but were 37.1 ± 12 , 80.3 ± 10.3 , and 174 ± 12.5 for group II respectively, ($p > 0.05$).

The mean IELT and IIEF pretreatment were 37 ± 11.24 sec. And 13.2 ± 4.2 for the group I, while in group II was 35.98 ± 10.8 sec. And 13.12 ± 4.11 respectively, there was no statistically significant difference between both groups ($p = 0.55$ and 0.94 respectively) (Table 1).

At the end of 3 months, the mean value of IELT in group I showed a highly significant improvement from 37 ± 11.24 sec to 120.5 ± 47.37 sec. ($p\text{-value} < 0.001$). While in group II, the mean values of IELT showed no significant improvement from baseline 35.98 ± 10.8 sec. to endpoint 39.43 ± 13.6 sec. ($p\text{-value} > 0.05$).

As regarding the IIEF, there was a highly significant improvement from baseline 13.2 ± 4.2 to endpoint 20.45 ± 4.5 in group I ($p\text{-value} < 0.001$) while there was no statistically significant difference in group II from baseline 13.12 ± 4.11 to endpoint 15 ± 4.84 ($p\text{-value} > 0.05$) (table 2).

Regarding IIEF-5 scores, the ED patients were divided into three grades as severe ED (score: 1–7), moderate ED (8–11), and mild ED (11–21). All grades of ED showed a statistically significant difference in IELT in group I ($p < 0.01$) versus placebo. However, there was no significant difference between the grades of ED from baseline to endpoint ($p = 0.029$; $p = 0.46$ (table 3–4).

At the end of 2 years follow up of tadalafil group after stoppage of tadalafil, there was still significant difference in comparison with baseline data, although the readings of IIEF and IELT values decreased slightly than the previous values after 3 months treatment (table 5) .

The common side effects were headache in 13 patients (16.25 %), Lower back pain by 11 patients (13.75 %), dyspepsia in 8 patients (10 %), gastroesophageal reflux in 4 patients (5.0 %), and myalgia in 3 patients (3.3%). Most of the side effects disappeared spontaneously over time.

Discussion

The relationship between erectile dysfunction and premature ejaculation was hypothesized by **Janini et al.** ^[14] as he declared a continuous circle between both PE and ED as the trial to delay the ejaculation decreases stimulation and produces ED. The attempt to attain an erection by constant repeated stimulation ends in rapid ejaculation and stress with frustration.

In this scenario, PE occurs 2ry to increased sexual arousal to attain erection with anxiety that increases sympathetic stimulation and produces PE. ^[14]

The current therapies for PE nowadays are behavioral therapies, anesthetic agents topically, selective serotonin reuptake inhibitors (SSRIs), recently phosphodiesterase inhibitors 5 (PDE5) have a significant role in PE treatment ^[15].

In a retrospective study, **Karabakan et al.** ^[16] found that tadalafil 5 mg alone for three months improved significantly all measured parameters (p values < 0.001) where this study included 60 patients diagnosed with erectile dysfunction mean baseline scores were 2.2 ± 1.4 min for IELT and 9.5 ± 3.7 for IIEF-5, the endpoint was 3.4 ± 1.9 min and 16.1 ± 4.7 , for IELT and IIEF respectively. Also, tadalafil increases the IELT in all three ED groups (severe, moderate, and mild ED groups). There was a statistically significant difference between the pre-and post-treatment values of IELT variables ($p < 0.01$) in all groups. Still, there was no statistically significant difference between the ED groups in terms of IELT, and this result comparable with the current study.

McMahon et al. ^[15] in a well-designed study to assess the efficacy of sildenafil in men with PE compared to placebo, founded increased overall sexual satisfaction with improved control over ejaculation but without significant improvement in IELT.

Our study investigated the effect of tadalafil 5 mg daily on ED and PE after three months of medical treatment compared with placebo, and there was a significant improvement in IIEF and IELT. These

findings disagree with the results of **McMahon et al.** ^[15] mentioned before.

Although our results agree with **Salonia et al.** ^[17] that founded significant improvement of IELT and overall sexual satisfaction and decreased the stress.

The 1st known study to assess the effect of tadalafil 5 mg daily on PE that was done by **Ozcan et al.** ^[18] founded significant improvement in IELT in patients with lifelong PE. These results comply with our study results that showed improved IELT up to 2.3 m.

In all ED grades (mild, moderate, and severe), there was a statistically significant improvement of IELT before and after treatment. Still, it was not statistically significant between the grades, and these results agree with **Karabakan et al.** ^[16], who founded comparable results.

In the current study, there was a significant improvement in erectile function and overall sexual satisfaction with significant improvement in IIEF compared to placebo. These results were supported by **Karabakan et al.** ^[16], who studied 60 patients with sexual dysfunction and founded significant improvement of IIEF and IELT.

Another double-blind placebo-controlled study done by **Mattos et al.** ^[19] to assess the effect of tadalafil 20 mg alone or fluoxetine in PE revealed better improvement in combined tadalafil and fluoxetine than each drug alone.

Regarding side effects in our study, most of the side effects were mild and tolerable. No patient discontinued the medications due to these side effects in the form of headache, myalgia, and lower back pain.

Our side effects results agree with **Karabakan et al.** ^[16], who founded mild side effects symptoms that disappeared over time in the form of headache, muscle, low back pain, and flushing.

To our knowledge, our study is the first study to assess the long-term follow up results of patients after stoppage of tadalafil and revealed persistence of significant long term improvement.

We concluded that a daily Tadalafil 5 mg oral tablet is an effective, tolerable, and safe treatment option for patients with erectile dysfunction and premature ejaculation and we noticed significant long-term improvement after stoppage of tadalafil.

Abbreviations

(IIEF-5)

International index of erectile function questionnaire-5

(IELT)

Intravaginal ejaculatory latency time

(PE)

Premature ejaculation

(ED)

Erectile dysfunction

(PDE5i)

Phosphodiesterase-5 inhibitors

The Main Points

1. PE is coexisting with ED in 30 % of patients.
2. International index of erectile function Questionnaire-5 (IIEF-5) and intravaginal ejaculation latency time (IELT) is used to evaluate the erectile dysfunction and premature ejaculation, respectively.
3. IELT has higher sensitivity and specificity for the evaluation of PE.
4. Daily Tadalafil 5 mg for 3 months is an effective, tolerable, and safe treatment for patients suffering from ED and PE and still effective after stoppage for 2 years

Declarations

1. Competing interests: The authors declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

2. Funding: The authors received no financial support for the research, authorship and/or publication of this article.

3. Informed consent for participation and publish: Informed written consent was obtained from all patients before the study for participation and publish.

4. Ethical approval The protocol and written informed consent were approved by the local ethical committee of at Al-Azhar university, faculty of medicine (Alhussin hospital) Uro-Surg./D/2018/0023

5. Acknowledgements: None

6. Availability of data and materials: The data that support the findings of this study are available from the corresponding author upon request.

7. Authors' Contributions:

All listed authors (TG., IA, AE., ES., and AS.) have performed all four points specified below:

- A. Made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data.
- B. Involved in drafting the manuscript or revising it critically for important intellectual content.
- C. Provided final approval of the version to be published. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.
- D. Agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

All authors read and approved the final manuscript and confirm that all methods were carried out in accordance with relevant guidelines and regulations.

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Tables

Table (1): Patient demographics and baseline and clinical characteristics: Tadalafil versus placebo.

Total N=160

Parameters	Tadalafil N=80	Placebo N=80	P-Value
Age (years)			0.68 NS
Mean $\pm$ SD	36.3 $\pm$ 11.6	37.1 $\pm$ 12	
Range (Max-Min)	41(18-59)	40(18-58)	
Weight (Kg)			0.52 NS
Mean $\pm$ SD	78.9 $\pm$ 8.4	80.3 $\pm$ 10.3	
Range (Max-Min)	19(69-88)	18(71-89)	
Height (cm)			0.77 NS
Mean $\pm$ SD	171.3 $\pm$ 14.6	174 $\pm$ 12.5	
Range (Max-Min)	22(159-181)	21(160-181)	
IELT before			0.55 NS
Mean $\pm$ SD	37 $\pm$ 11.24	35.98 $\pm$ 10.8	
Range (Max-Min)	47(10-57)	48(10-58)	
IIEF before			0.94 NS
Mean $\pm$ SD	13.2 $\pm$ 4.2	13.12 $\pm$ 4.11	
Range (Max-Min)	16(4-20)	16(4-22)	

+Data are presented as mean $\pm$ standard deviation.

*Independent sample t-test was used

+p-value is significant if $p < 0.05$.

Key words: SD = standard deviation, IELT = intravaginal ejaculatory latency time, IIEF = international index of erectile function questionnaire 5.

Table (2): Comparison of Patient clinical characteristics at baseline and endpoint: Tadalafil versus placebo. Total N=160

Parameters	Tadalafil N=80			Placebo N=80			++P2
	<i>Baseline</i>	<i>Endpoint</i>	<i>Change</i>	<i>Baseline</i>	<i>Endpoint</i>	<i>Change</i>	
IELT							< 0.001 HS
Mean $\pm$ SD	37 $\pm$ 11.24	120.5 $\pm$ 47.37	-83.47	35.98 $\pm$ 10.8	39.43 $\pm$ 13.6	-3.45	
+P1	< 0.001 HS			0.042 S			
IIEF							< 0.001 HS
Mean $\pm$ SD	13.2 $\pm$ 4.2	20.45 $\pm$ 4.5	-7.27	13.12 $\pm$ 4.11	15 $\pm$ 4.84	-1.87	
+P1	< 0.001 HS			0.013			

*Data are presented as mean $\pm$ standard deviation.

→p-value is significant if p<0.05.

+P1: Baseline versus endpoint, *Paired sample t-test was used

++P2: Endpoint of Tadalafil versus Placebo group, Independent sample t-test was used

Key words: SD = standard deviation, IELT = intravaginal ejaculatory latency time, IIEF = international index of erectile function questionnaire 5.

Table (3): Comparison of ED groups in terms of IELT scores before and after Tadalafil 5mg daily treatment. Total N=80

IELT scores	Tadalafil N=80			P1-Value ⁺
	<i>Baseline</i>	<i>Endpoint</i>	<i>Change</i>	
Mild, N=47				<0.001 S
Mean $\pm$ SD	37.5 $\pm$ 12.2	127.85 $\pm$ 46.7	90.35	
Moderate, N=26				<0.001 S
Mean $\pm$ SD	34.8 $\pm$ 10.1	121.5 $\pm$ 45.7	86.7	
Severe, N=7				<0.001 S
Mean $\pm$ SD	42.14 $\pm$ 6.9	67.6 $\pm$ 18.98	25.46	
P2-Value⁺⁺	0.29	0.46		

Data are presented as mean $\pm$ standard deviation.

→p-value is significant if $p < 0.05$.

+P1: Baseline versus endpoint, *Paired sample t-test was used

++P2: Comparison of IELT 3 scores, F-test (Anova) was used

Key words: SD = standard deviation, IELT = intravaginal ejaculatory latency time,

Table (4): Comparison of ED groups in terms of IELT scores before and after Placebo. Total N=80

IELT scores	Placebo N=80			P1-Value ⁺
	<i>Baseline</i>	<i>Endpoint</i>	<i>Change</i>	
Mild, N=49				>0.05 NS
Mean $\pm$ SD	36.24 $\pm$ 11.8	37.6 $\pm$ 13.8	1.36	
Moderate, N=24				0.005 S
Mean $\pm$ SD	33.7 $\pm$ 8.9	42.5 $\pm$ 13.8	8.8	
Severe, N=7				>0.05 NS
Mean $\pm$ SD	42.14 $\pm$ 6.86	41.85 $\pm$ 11.13	0.29	
P2-Value⁺⁺	0.18	0.15		

Data are presented as mean $\pm$ standard deviation.

→p-value is significant if $p < 0.05$.

+P1: Baseline versus endpoint, *Paired sample t-test was used

++P2: Comparison of IELT 3 scores, F-test (Anova) was used

Key words: SD = standard deviation, IELT = intravaginal ejaculatory latency time,

Table (5): Comparison of Patient clinical characteristics at baseline and after 2 years Tadalafil 5 mg administration. Total N=75

Parameters	Tadalafil N=75			P- Value
	<i>Baseline</i>	<i>Endpoint</i>	<i>Change</i>	
IELT				<i>< 0.001 HS</i>
Mean $\pm$ SD	37 $\pm$ 11.24	98 $\pm$ 18.3	-61	
IIEF				<i>< 0.001 HS</i>
Mean $\pm$ SD	13.2 $\pm$ 4.2	19.1 $\pm$ 2.3	-5.9	

*Data are presented as mean $\pm$ standard deviation.

→p-value is significant if $p < 0.05$.

*Independent sample t-test was used