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A DOUBLE BLIND RANDOMIZED PLACEBO CONTROLLED STUDY OF TADALAFIL VS PLACEBO IN PREMATURE EJACULATION

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ABSTRACT To Assess the effectiveness of Tadalafil when used daily compared with Placebo in lifelong Premature Ejaculation. To Assess if Tadalafil when used alone is helpful in premature ejaculation. 109 patients diagnosed with lifelong Premature Ejaculation were randomly given either Tadalafil 10 mg or Placebo. Baseline Intra Vaginal Ejaculatory Latencytime [IELT] and IELT after 4 weeks treatment were done using stopwatch and results analysed. In order to examine the pre and post treatment IELT, Mean score analysis, Standard Deviation and paired 't' test has been used in this research. It is found from this study that Group I patients have significant increase in IELT post treatment while there is no such increase in Group II patients.

1. INTRODUCTION

Premature Ejaculation is simply defined as a condition in which a male recurrently achieves orgasm and ejaculation before he wishes to do so. [1] Of the various definitions of Premature Ejaculation, the most comprehensive are by 1. The International Society Of Sexual Medicine [ISSM 2013] [2] see Table-1 and 2.Diagnostic and Statistical Manual of Mental Disorders Fifth Edition [3] .see Table-1.

Table 1 : Definitions of Premature Ejaculation established through consensus committees and / or Professional organizations

No.	DEFINITION	SOURCE
1.	A male sexual dysfunction characterized by ejaculation which always occurs prior to or within one minute of vaginal penetration , either present from the first sexual experience or following a new bothersome change in ejaculatory latency and the inability to delay ejaculation on all all or nearly all vaginal penetrations, and negative personal consequences such as distress, bother, frustration and/or the avoidance of sexual intimacy.	The International Society Of Sexual Medicine 2013[2]
2.	• Persistent or recurrent pattern of ejaculation occurring during partnered sexual activity within approximately one minute following vaginal penetration and before the individual wishes it. • The symptom in criteria A must have been present for atleast six months and must be experienced on almost all or all [approximately 75% to 100%] occasions of sexual activity. • The symptoms in criteria A causes clinically significant distress in the individual • The sexual dysfunction is not better explained by a non sexual mental disorder or as a consequence of severe relationship distress or other significant stressors and is not attributable to the effects of a substance use/medication or another medical disorder	Diagnostic And Statistical Manual of Mental Disorders Fifth Edition[3]

The prevalence of Premature Ejaculation as reported in the literature varies between 20-40% [4,5]. But as per the guidelines of the The International Society Of Sexual Medicine 2013[2], the prevalence of Premature Ejaculation is only about 4%. This is due to the new criteria of Premature Ejaculation by both ISSM 2013[2],and DSM 5 criteria [3].

The etiology of Premature Ejaculation[according to the guidelines released by ISSM 2013[2] is 1. not known.2. To date no biological factor has been shown to be causative in the majority of men with premature ejaculation .

In private practice serotonin specific reuptake inhibitors [SSRI'S] are the drug of choice in Premature Ejaculation [6,7,8,9].Many a times patients who were started on SSRI's were anxious after knowing that it is basically a drug used for treating depression or anxiety diorders. They felt that they have a sexual problem not a psychiatric one.

Ironically though Premature Ejaculation is a psychiatric disorder as per both ICD 10[10], and DSM 5 criteria [3], patients tend to think differently.

Because of this they frequently ask about sideeffects,duration of treatment ,and whether they will become addicted to these drugs.

So thinking from the patient's perspective Tadalafil was tried in Premature Ejaculation in this study.

Though there are many studies using Tadalafil in Premature Ejaculation , the dosage used in this studies is 20 mg and it is taken as and when needed only. [not daily]

There are of course many studies on using Tadalafil in daily basis for Erectile Dysfunction [E.D]. Such type of studies in Premature Ejaculation [P.E] are rare.

This study is an attempt to bridge that gap.

1. MATERIALS AND METHODS

This study was conducted among 105 patients who presented to a psychiatric outpatient clinic between April 2015 to April 2016 with history of lifelong Premature Ejaculation [P.E] and a self reported. Intra Vaginal Ejaculatory Latency Time [IELT] of < 1 minute.[2,3].

A written informed consent was obtained from all persons participating in the study.

2. INCLUSION CRITERIA

1. Intra vaginal ejaculatory latency time [IELT] of < 1 minute [2,3].
2. A cut-off score of > 11 or = 11 in Premature Ejaculation Diagnostic Tool. [12]
3. Those who have experienced Premature Ejaculation since their first sexual experience on every / almost every attempt [2].

3. EXCLUSION CRITERIA

1. Patients with history of substance abuse.
2. Patients with any comorbid medical illness
3. Patients with associated Erectile Dysfunction

A physical /genital examination was done for all these patients. Following which they were administered Premature Ejaculation Diagnostic Tool [PED] [12], which is a screening questionnaire for

P.E.

In these patients a baseline assessment of IELT was done by their partner using a stopwatch and those with IELT< 1minute were only included in the study.[an average of three consecutive IELT was taken].

These patients were randomly assigned to either Tadalafil 10 mg or placebo on a daily basis.54 patients were on Tadalafil [Group 1] , and 54 were on placebo [group 2].

All these patients were married and were in the age group 25 to 45.

The IELT was calculated again, as before, after 4 weeks and results analysed.

4. RESULTS AND DISCUSSION :

In the following tables, 52 patients have considered for Group I and 53 patients have taken for Group II. The results of the Group I and Group II patients are discussed in the following tables with the help of statistical results.

Group 1 :
Table No. 2 : Age of the patients and pre treatment intravaginal ejaculation latency time

S. No.	Age	Frequency	%	Mean Score	SD	't' Test	'p' Value
1.	Upto 30 years	29	55.8	49.21	5.73	1.899	>0.05
2.	Above 30 Years	23	44.2	49.52	5.42		
	Total		.0	49.35			

Table No. 3 : Age of the patients and post treatment intravaginal ejaculation latency time

S. No.	Age	Frequency	%	Mean Score	SD	't' Test	'p' Value
1.	Upto 30 years	29	55.8	195.52	4.49	0.887	>0.05
2.	Above 30 Years	23	44.2	194.17	4.12		
	Total		.0	194.92			

Table No. 4 : Educational qualification of the patients and pre treatment intravaginal ejaculation latency time

S. No.	Educational Qualification	Frequency	%	Mean Score	SD	't' Test	'p' Value
1.	School level	35	67.3	51.97	4.01	5.107	<0.05
2.	College level	17	32.7	43.94	4.21		
	Total	52	100.0	49.35			

Table No. 5 : Educational qualification of the patients and post treatment intravaginal ejaculation latency time

S. No.	Educational Qualification	Frequency	%	Mean Score	SD	't' Test	'p' Value
1.	School level	35	67.3	194.23	4.55	2.051	>0.05
2.	College level	17	32.7	196.35	3.59		
	Total	52	100.0	194.92			

Table No. 6 : Pre and Post treatment intravaginal ejaculation latency time

S. No.	Time	Frequency	%	Mean Score	SD	't' Test	'p' Value
1.	Pre	52	50.0	49.35	5.544	145.83	<0.001
2.	Post	52	50.0	194.92	4.342		
	Total		.0				

After 4 weeks of treatment, IELT is increased in Group 1 patients. Mean pre treatment value (49.35 in Table 2,4,6) and mean post treatment value (194.92 in Table 3,5,6) and it is statistically significant (p<0.001 in Table 6).

Further, pre treatment IELT is less (Mean Score 43.94 in Table 4) among the college level educated patients when compared to school level educated patients (Mean Score 51.97 in Table 4) and it is statistically significant (p<0.05 in Table 4).

Group 2 :
Table No. 7 : Age of the patients and pre treatment intravaginal ejaculation latency time

S. No.	Age	Frequency	%	Mean Score	SD	't' Test	'p' Value
1.	Upto 30 years	24	45.3	51.46	6.32	0.250	>0.05
2.	Above 30 Years	29	54.7	50.97	6.40		
	Total	53	100.0	51.19			

Table No. 8 : Age of the patients and post treatment intravaginal ejaculation latency time

S. No.	Age	Frequency	%	Mean Score	SD	't' Test	'p' Value
1.	Upto 30 years	24	45.3	56.50	5.82	0.844	>0.05
2.	Above 30 Years	29	54.7	55.03	6.00		
	Total	53	100.0	55.70			

Table No. 9 : Educational qualification of the patients and pre treatment intravaginal ejaculation latency time

S. No.	Educational Qualification	Frequency	%	Mean Score	SD	't' Test	'p' Value
1.	School level	40	75.5	54.08	2.80	8.303	<0.05
2.	College level	13	24.5	42.31	5.81		
	Total	53	100.0	51.19			

Table No. 10 : Educational qualification of the patients and post treatment intravaginal ejaculation latency time

S. No.	Educational Qualification	Frequency	%	Mean Score	SD	't' Test	'p' Value
1.	School level	40	75.5	57.88	4.36	1.116	>0.05
2.	College level	13	24.5	49.00	5.02		
	Total	53	100.0	55.70			

Table No. 11 : Pre and Post treatment intravaginal ejaculation latency time

S. No.	Time	Frequency	%	Mean Score	SD	't' Test	'p' Value
1.	Pre	52	50.0	51.19	6.306	1.442	>0.05
2.	Post	52	50.0	55.70	5.908		
	Total		.0				

In Group 2, mean pre treatment IELT (51.19 in Tables 7,9,11) and mean post treatment IELT (55.70 in Tables 8,10,11) and it is not statistically significant (p>0.05 in Table 11).

Further, pre treatment IELT is less (Mean Score 42.31 in Table 9) among the college level educated patients when compared to school level educated patients (Mean Score 54.08 in Table 9) and it is not statistically significant (p<0.05 in Table 9).

6. CONCLUSION

In this study, the researcher has mainly examined the pre and post treatment IELT in Group I and Group II patients. This study cleared that in Group I, mean pre and post treatment IELT is statistically significant. While in Group II, mean pre and post treatment is not statistically significant. Further, the school level educated patients are having high IELT score in pre treatment when compared to college level educated patients.

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