ON DEMOND SILDOSIN 4MG VS DAPOXITINE 60MG IN TREATMENT OF PRIMARY PREMATURE EJACULATION

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Introduction

Premature ejaculation (PE) is a common sexual problem encountered by men in day-to-day clinical practice. It affects about 20-30% of men in the sexually active age group. PE is a commonly used term, but it is more appropriately called early ejaculation or rapid ejaculation ***(Raveendran and Agarwal, 2021)***.

PE means ejaculation occurs within one minute during the sexuality with sex partner after inserting into the vagina, and this symptom lasts for at least 6 months. PE is defined by The American Urology Association as "ejaculation occurring sooner than desired causing distress to one or both partners" ***(Gillman and Gillman, 2019)***.

The etiology of PE is complex, and its pathogenesis is still unclear. It's believed that this disease is mostly related to psychological factors. The persistent unhealthy psychological factors may aggravate potential abnormal organic factors, which lead to the occurrence of premature ejaculation ***(Coskuner and Ozkan, 2022)***.

While PE is a common sexual dysfunction affecting all age groups, it is more prominent in older age groups and more commonly associated with other medical conditions like diabetes. Primary PE can be triggered by psychological impulses like conditioning, upbringing, or traumatic sexual experience. Secondary PE can be triggered by diabetes, hypertension, hyperthyroidism, alcoholism, or use of recreational drugs ***(Raveendran and Agarwal, 2021)***.

According to the time when the symptom of PE occurs, this disease could be divided into two types which are named preliminary premature ejaculation and acquired premature ejaculation ***(Pereira-Lourenço et al., 2019)***.

PE causes psychological stress and loss of self-esteem, resulting in significant adverse effects on the quality of life, of both the patient and the partner. So, present therapeutic schedule mainly includes psychological

therapy, behavioral therapy, drug therapy and Chinese medicine. These therapies could be used alone or in combination, and relevant literature has reported certain clinical effects.

However, there are still many problems such as large side effects, high recurrence rate, and long-term efficacy uncertainty, which need to concentrate on ***(Abbas et al., 2023)*.**

Thus, pharmacotherapy should in theory be the treatment of choice for patients with lifelong PE **(Waldinger MD, et al .,2020).**

Dapoxetine is a selective serotonin reuptake inhibitor, is the first oral pharmacological agent indicated for the treatment of men aged 18-64 years with premature ejaculation. **(N Engl J Med. 2019)**.

Dapoxetine is the only effective and safe available on-label oral treatment for PE, and its use can result in better quality of life for the patient and their sexual partner. **(N Engl J Med. 2019)**.

Oral dapoxetine 60 mg (administered as needed) was effective in the treatment of men with premature ejaculation, inducing significantly greater improvements. **(N Engl J Med. 2019)**.

Silodosin is a selective alpha-1a adrenergic antagonist used in the therapy of benign prostatic hypertrophy. Silodosin is associated with a low rate of serum aminotransferase elevations and to rare instances of clinically apparent acute liver injury. **(N Engl J Med. 2019)**.

Silodosin inhibits alpha adrenergic receptors present on smooth muscle in the bladder neck and prostate (alpha-1a adrenergic receptors)**(N Engl J Med. 2019)**.

Compared with other α1-adrenoceptor antagonists, silodosin appeared to suppress ejaculation in a relatively higher percent of trial participants.

This suppression of ejaculation by silodosin suggested its potential for treating premature ejaculation and it seemed to be more effective for preventing PE than other alpha blockers. **(Sato Y, Otani T,et al. 2017).**

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Aim of the Work

The aim of this study is to assess efficacy and tolerability of Silodosin 4mg vs Dapoxitine 60mg in treatment of primary premature ejaculation.

Patients and Methods

A prospective study will be carried out on 50 patients with premature ejaculation who attending outpatient clinic, urology department, Benha university hospitals over a period of 6 months starting from approval of the institutional ethical committee.

An informed written consent will be obtained from the patients. Every patient will receive an explanation of the purpose of the study and will have a secret code number.

Research results will only be used for scientific purposes. Any unexpected risks appearing during research will be clarified to the participants and to the ethical committee on time.

Inclusion Criteria:

- Age > 18 years old.
- Patients with primary premature ejaculation (PPE) according to (IELT < 1 min)
- Sexually active.
- Heterosexual.
- The course of suffering from PE is ≥6 months.

Exclusion criteria:

- History of diabetes and other diseases.
- Uncontrolled hypertension (HTN) (systolic ≥ 140 mmHg or diastolic ≥ 90 mmHg).
- Patients having anatomic abnormalities of the penis or genital region
- Patients' refusal.
- Patients with erectile dysfunction.
- Patient with chronic prostatitis.
- Patient with psychologically disorder.
- Patient on anti-psychiatric drugs.

Study design:

Patients who meet the previous criteria will be enrolled in the study.

We randomly assigned 80 outpatients with PPE to two groups , group A (sildosin 4mg) 40 patients and group B (dapoxatine 60mg) 40 patients .

Methods:

All patients meeting the above-mentioned criteria will be subjected to the following:

1. **Full history taking including:**

Personal, present, past, family, and surgical histories of the patients will be documented. This includes collecting information about the patient's demographics, current health status, medical history, family medical history, and any prior surgical procedures.

2. **Clinical Examination:**

A thorough clinical examination of the patients will be conducted to evaluate their general health and assess any physical signs and symptoms related to premature ejaculation or other conditions.

Group A (sildosin 4 mg): intake 2h before intercourse (on demand) at least 6 times intercourse /month for 2 months.

Group B (dapoxatine 60mg): the same like sildosin.

Follow up patients will be evaluated by by PEP (premature ejaculatory profile) & IELT. (intravaginal latency time) 2 months after start of treatment.

Intravaginal ejaculatory latency time (IELT): normal duration 2.5- 5 minutes. **(Waldinger MD, et al .2005).**

scores of the Premature Ejaculation Profile (PEP): to evaluate the reliability and validity of the Premature Ejaculation Profile (PEP), The

PEP contains four measures: perceived control over ejaculation, personal distress related to ejaculation, satisfaction with sexual intercourse, and interpersonal difficulty related to ejaculation, each assessed on five-point response scales. **(Patrick DL, et al .,2009).**

Any side effects of drugs will be recognized and recorded.

Ethical considerations:

1. An approval from the Research Ethics Committee of faculty of medicine will be obtained.
2. An informed written consent from all patients or first-degree relatives before participation will be obtained; it will include data about aim of the work, study design, site, time, subject and methods, confidentiality.
3. Official permission will be obtained from the Dean of Faculty of Medicine and the administrators of University Hospitals to conduct this study.

Results

The results will be tabulated, correlated and statistically analyzed to fulfill the aim of the work.

Statistical analysis

We will use IBM's Statistical Package for the Social Sciences (2017, Released) to edit, code, and tabulate the data we gathered. IBM Corp., Armonk, New York, USA: IBM SPSS Statistics for Windows, Version 25.0. To ensure that the data was distributed normally, the Shapiro-Wilk test was employed. Each parameter's data type informed the presentation and analysis of the corresponding data. Nominal data were expressed as mean ± SD. For categorical data, percentages and frequencies were employed. The statistical significance of a difference between two study groups for parametric variables was assessed using an independent samples t-test, and for non-parametric variables, the Mann Whitney Test (U test) was employed. We looked examined the correlation between the two qualitative variables using the Chi-Square test. At a 95% confidence interval, a p-value is deemed significant if it is less than 0.05.

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