

## **Abstract**

**Title of the abstract:** The efficacy and safety of Clomipramine Hydrochloride versus Dapoxetine Hydrochloride in Married Heterosexual Men with Premature Ejaculation: A Pragmatic, Randomized Controlled Trial

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### **Background:**

Dapoxetine and Clomipramine are used in treatment of premature ejaculation. Previous trials have demonstrated advantages for Dapoxetine compared to other SSRIs in increasing IELT (intravaginal ejaculatory latency time), and reducing distress due to premature ejaculation, but no head to head comparisons have been conducted against Clomipramine that has been shown to be effective in treatment of premature ejaculation.

### **Objective:**

Objective of the study was to evaluate the efficacy and safety of six weeks of daily oral Clomipramine (25-50 mg) versus Dapoxetine on demand (30 mg; once a week for six weeks or for six doses) in the treatment of Premature Ejaculation in heterosexual, married men.

### **Methods:**

**Design:** A pragmatic, randomized, parallel group, allocation-concealed, assessor-blinded, active-controlled trial.

**Setting:** Urology and Psychiatry department outpatient services of a teaching general and multi-specialty referral hospital in south India.

**Participants:** Eighteen married adults presenting with premature ejaculation as a result of a non-organic etiology and fulfilling selection criteria, providing informed consent for participation. The target sample size is 120 and the study is ongoing.

**Interventions:** Oral Clomipramine (25 mg daily for 1st week and 25-50 mg for subsequent 5 weeks, depending on participants' preference) or oral Dapoxetine 30 mg on demand (taken 1-3 hours before intercourse) for 6 doses (recommended once

weekly for 6 weeks). Additional non-pharmacological interventions were delivered by the means of a structured psycho-education module.

**Main outcome measures:** The primary outcome is the improvement of premature ejaculation at six weeks (or after the first six sexual encounters) which was measured by validated patient-reported measures (1) the Premature Ejaculation Profile (PEP) that measures changes in the participants subjective sense of control over ejaculation, distress related to PE, interpersonal difficulty and satisfaction with sexual intercourse, and (2) Clinical Global Impression of Change (CGI-C). Secondary outcomes were adverse effects of the interventions using ASEC side effects rating scale, and drug discontinuation.

### **Results:**

Eighteen patients have been recruited thus far in this ongoing study. Two of them have completed the study, both in Clomipramine arm. One patient in Dapoxetine arm has dropped out after third week of study, due to adverse drug reactions of insomnia and dry mouth. Analysis was done by intention to treat. All three of the participants showed trajectory towards improvement in all four domains of PEP. One patient in Clomipramine arm reported CGI score of 2 (“better”) at the end of six weeks. However, analytical data of outcome measure done on these three patients was not statistically significant. Patients receiving Clomipramine reported adverse reactions of constipation and drowsiness.

Descriptive analysis of the baseline profile of patients recruited till now (N=18) showed that most of them were young, less than 10th standard educated, presenting mostly alone, with very poor control over their ejaculation, poor satisfaction from sexual intercourse, extremely distressed in relation to early ejaculation and experiencing moderate difficulty in interpersonal functioning due to premature ejaculation and have multiple sexual misconceptions-the most prominent being the size of the penis and a significant proportion of them have masturbatory guilt.

(Key words – Premature Ejaculation, Clomipramine, Dapoxetine)