



## INCIDENCE OF ANEJACULATION IN PATIENTS WITH BENIGN PROSTATIC HYPERPLASIA RECEIVING SILODOSIN 8mg - A PROSPECTIVE STUDY

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Authors

[G Chengalvarayan](#)<sup>1</sup>, [B Sivasankaran](#)<sup>2</sup>, [G Sivasankar](#)<sup>3</sup>

<sup>1</sup> Associate Professor, Institute of Urology, Madras Medical College & RGGGH, Chennai, India

<sup>2</sup> Senior Resident, Institute of Urology, Madras Medical College & RGGGH, Chennai, India

<sup>3</sup> Director(Retd), Institute of Urology, Madras Medical College & RGGGH, Chennai, India

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**Corresponding Author:** [B Sivasankaran](#)

**Email:** [drsbss108@gmail.com](mailto:drsbss108@gmail.com)

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### Abstract

#### Background:

Silodosin, a selective  $\alpha 1A$ -adrenoceptor blocker, improves Lower Urinary Tract Symptoms (LUTS) in Benign Prostatic Hyperplasia (BPH) by relaxing smooth muscle in the prostate and bladder neck. Its receptor specificity, however, predisposes patients to ejaculatory dysfunction, particularly Anejaculation, which may affect compliance. This study aimed to determine the region-specific incidence and characterize the pattern of ejaculatory changes in Sexually active men receiving Silodosin 8 mg daily for BPH.

#### Patients and Methods:

A prospective, questionnaire-based descriptive study was conducted at the Institute of Urology, Madras Medical College–Rajiv Gandhi Government General Hospital, Chennai, India, from December 2023 to May 2024. Sixty-six sexually active men with a clinical diagnosis of BPH, newly initiated on Silodosin 8 mg once daily, were enrolled. Data on demographic profile, perception of ejaculatory change, frequency, and type of dysfunction, compliance to treatment were obtained using a structured questionnaire.

#### Results:

Most participants were 55–60 years old (63.6%). Overall, 95.5% reported an ejaculatory change, of which 80.3% experienced it with every sexual act. Anejaculation was observed in 22.7% of patients, while 72.7% reported reduced ejaculate volume. Regarding treatment adherence, 65.1% continued therapy without interruption, 24.2% continued despite concerns, and only 6.0% discontinued due to ejaculatory dysfunction.

#### Conclusion:

Silodosin 8 mg is frequently associated with ejaculatory dysfunction, with anejaculation occurring in 22.7% of sexually active men. Despite these side effects, most patients continued therapy, highlighting the importance of counselling about potential sexual adverse events to support adherence and informed decision-making

**Keywords:** Silodosin, Benign prostatic hyperplasia, Anejaculation, Ejaculatory dysfunction

## Introduction

Benign prostatic hyperplasia (BPH) is a progressive, non-malignant enlargement of the prostate gland, occurring in up to 50% of men over 50 to 60 years, and its predominance increases further with age. BPH results from the noncancerous prostate gland enlargement induced by cellular hyperplasia of both glandular and stromal components.<sup>1</sup> The diagnosis of symptomatic BPH is generally based on the physical examination which reveals a diffusely enlarged, firm, and non-tender prostate supported by the storage and voiding symptoms.<sup>2</sup> BPH is a leading cause of lower urinary tract symptoms (LUTS), which frequently impair quality of life and increase healthcare utilization.<sup>3</sup>

$\alpha$ 1-adrenergic receptor antagonists are widely recommended as first-line pharmacotherapy for LUTS attributable to BPH because they rapidly and sustainably improve urinary flow and symptom burden. Among these agents, Silodosin, a highly selective  $\alpha$ 1A-adrenoceptor antagonist, preferentially relaxes prostatic and bladder-neck smooth muscle and is associated with fewer cardiovascular effects than less selective blockers. Silodosin, was approved by the Food and Drug Administration (FDA) for treatment of BPH in 2008.<sup>4,5</sup>

However, high  $\alpha$ 1A selectivity of Silodosin is linked with a higher frequency of ejaculatory disturbances compared with other  $\alpha$ -blockers. Its action on the vas deferens, seminal vesicles

and ejaculatory ducts can impair seminal emission, commonly producing Anejaculation or markedly reduced ejaculate volume. Anejaculation (absence of emission of semen, despite orgasm) is typically reversible but can cause psychological distress, strain sexual relationships, and reduce adherence, particularly among sexually active men.<sup>6</sup>

Reported rates of silodosin-associated anejaculation vary (approximately 14–28%) in international series<sup>7,8</sup>, but most data are from Western and East Asian cohorts. Cultural differences in attitudes toward sexual health and reporting may influence observed incidence and treatment acceptance, and published data from South India are also limited. Accordingly, we performed a prospective single-Institution study to measure the incidence of Anejaculation and describe related clinical outcomes in South Indian Men diagnosed with BPH and treated with silodosin 8 mg once daily.

This study is novel in its prospective design and focused evaluation of silodosin-induced anejaculation in an under-represented South Indian population. By systematically quantifying incidence and capturing patient experiences, it provides region-specific insights that can guide counselling, improve adherence, and support rational pharmacotherapy for BPH.

## **Patients and Methods**

### **Study design and setting**

This prospective descriptive study was carried out at the Institute of Urology, Madras Medical College–Rajiv Gandhi Government General Hospital (MMC-RGGGH), Chennai, India, between December 2023 and May 2024.

The protocol was approved by the Institutional Ethics Committee of Madras Medical College (IEC no: 07112023 dated 26.11.2023). All participants provided written informed consent, the study followed standard ethical principles.

### **Inclusion criteria**

Sexually active men (defined as engaging in sexual intercourse or masturbation) with a clinical and radiological diagnosis of BPH who were started on silodosin 8 mg once daily as first-line pharmacotherapy were included.

### **Exclusion criteria**

Prior prostate surgery or urethral instrumentation

Concurrent use of other  $\alpha$ -blockers or 5 $\alpha$ -reductase inhibitors (or medications known to impair ejaculation)

Neurological disease, systemic illness or pelvic/spinal trauma likely to affect ejaculation

Indwelling urethral catheter at the time of enrolment

Unwillingness to provide informed consent.

### **Sample size**

Sample size was estimated using the standard formula for proportions with 95% confidence and an absolute precision of 10%, assuming an expected anejaculation prevalence of ~25%. Based on this calculation, 66 consecutive eligible patients were enrolled.

### **Data collection and questionnaire**

Baseline demographic and clinical data were recorded for all patients. Ejaculatory function was assessed using a structured questionnaire adapted from Sakata and Morita (Appendix).<sup>9</sup>

The questionnaire recorded:

patient-reported perception of ejaculatory change, frequency of the change, type of change (anejaculation vs reduced volume), impact on medication adherence or discontinuation.

Follow-up evaluations were performed at one month after treatment initiation.

### **Statistical analysis**

Data were entered into Microsoft Excel and analysed with SPSS (IBM) version 25. Categorical variables are presented as frequencies and percentages; continuous variables as mean  $\pm$  SD. The incidence of anejaculation was calculated with 95% confidence intervals. Chi-square tests were used for categorical comparisons;  $p < 0.05$  was considered significant.

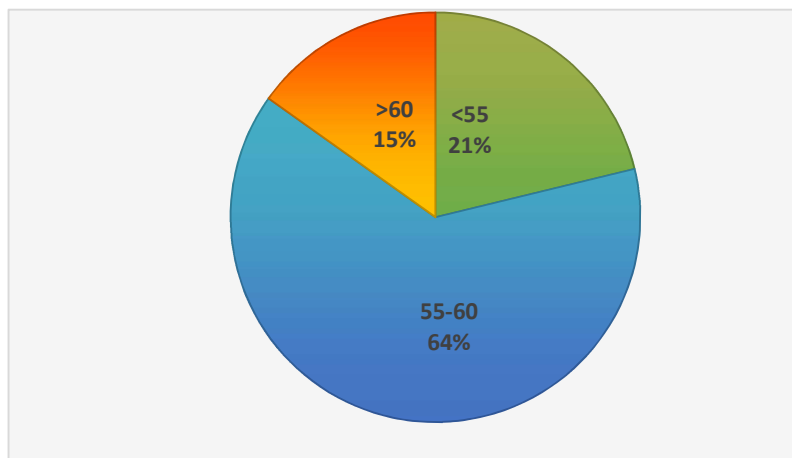
## Results

### Age Distribution:

A total of 66 sexually active male patients diagnosed with benign prostatic hyperplasia (BPH) and initiated on silodosin 8 mg once daily were enrolled in the study. The mean age of the cohort was  $57.2 \pm 3.0$  years (range: 52–64 years). Age stratification showed that 42 patients (63.6%) were in the 55–60-year group, followed by 14 patients (21.2%) aged <55 years, and 10 patients (15.2%) aged >60 years. This is consistent with the epidemiological trend of BPH where symptom onset and treatment initiation peak in the sixth decade, with a significant proportion extending into the early elderly age group.

**Table I.** Age distribution of the study population (n=66)

Age group (Years)	No of Patients	Percentage %
<55	14	21.2
55-60	42	63.6
>60	10	15.2
Total	66	100



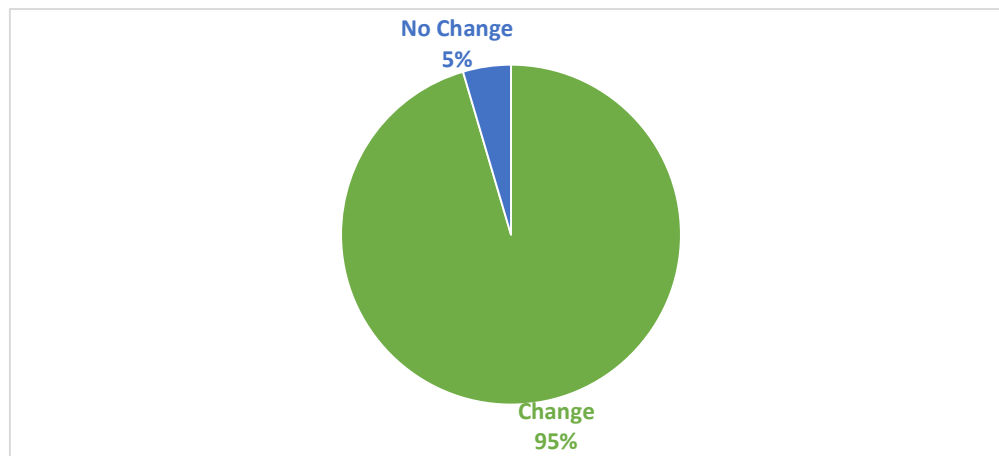
**Figure 1.** Pie chart showing age distribution of the study population .

### Perception of Ejaculatory Change

Out of 66 patients, 63 (95.5%) (95% CI: 91.0–100.0%) reported a noticeable change in ejaculatory function during treatment follow up, while only 3 (4.5%) reported no change. The difference was statistically significant ( $\chi^2 = 54.55$ ,  $p < 0.001$ ), confirming a strong association between silodosin therapy and ejaculatory dysfunction .

**Table II** demonstrates the proportion of patients reporting changes in ejaculation.

Perception of Ejaculatory Change	Number of Patients	Percentage (%)
Noticeable Change	63	95.5
No Change	3	4.5
Total	66	100



**Figure 2** Pie chart showing the proportion of patients reporting changes in ejaculation.

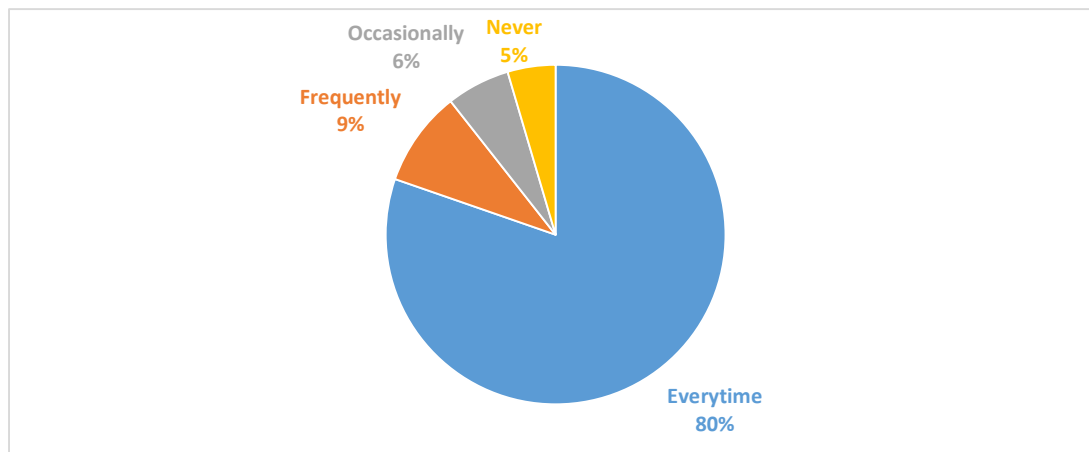
### Frequency of Ejaculatory Change :

Of the 66 men included in the study, most reported noticeable alterations in ejaculation after starting Silodosin therapy. The majority, 53 patients (80.3%), experienced changes with every ejaculation. A smaller subset, 6 patients (9.0%), described changes occurring in more than half of their sexual attempts, while 4 patients (6.0%) experienced such changes less frequently, in less than half of instances. Only 3 participants (4.5%) reported no disturbance in their ejaculatory pattern.

Overall, over 80% of the cohort experienced ejaculatory dysfunction consistently, ( $\chi^2 = 88.89$ ,  $p < 0.001$ ), which highlights the strong temporal relationship between silodosin therapy and ejaculatory dysfunction

**Table III** Frequency pattern of ejaculatory change among affected patients (n = 66)

Frequency of change	Number of patients	Percentage(%)
After every ejaculation	53	80.3
Frequently (>50% of times)	6	9.0
Occasionally (<50% of times)	4	6.0
No Change	3	4.5
Total	66	100



**Figure 3** Pie Chart showing frequency pattern of ejaculatory change

### Type of Ejaculatory Dysfunction

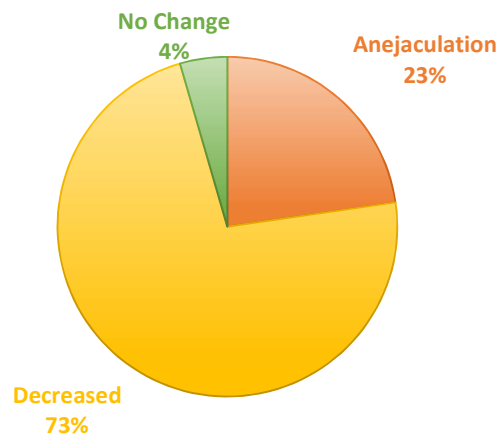
Among the study population of 66 patients, 15 (22.7%) experienced anejaculation while 48 (72.7%) reported reduced ejaculate volume and 3 patients (4.5%) experienced no side effects. In the overall cohort (n = 66) the incidence of anejaculation was 22.7% (15/66). The 95% confidence interval for this proportion, calculated by the standard normal approximation, is 12.6% to 32.8%.

Reduced ejaculate volume was significantly more frequent than anejaculation ( $\chi^2 = 18.82$ ,  $p < 0.001$ ), making it the predominant dysfunction.

These findings indicate that effects of Silodosin on ejaculatory function are not limited to a only reduction in volume for most patients; a sizeable population(22.7%) experience complete absence of seminal emission , a clinically relevant frequency given the potential impact on sexual satisfaction and treatment adherence.

**Table IV.** Type of ejaculatory dysfunction among the study population(n = 66)

Type of change	Number of patients	Percentage (%)
Anejaculation	15	22.7
Decreased ejaculate volume	48	72.7
No Change	3	4.5
Total	66	100



**Figure 4.** Pie chart showing distribution of ejaculatory dysfunction types

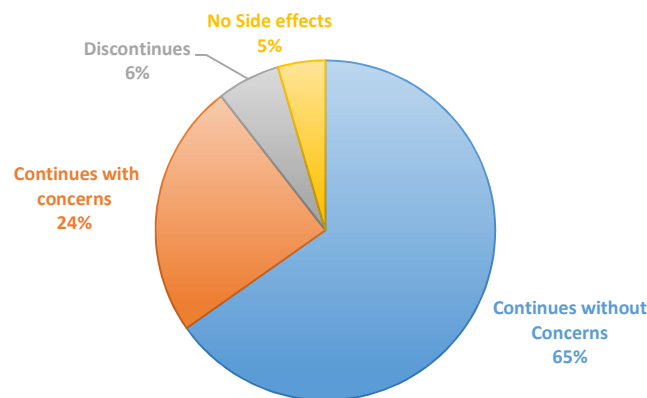
### Drug continuation status

At one month follow-up, 43 patients (65.1%) continued silodosin despite experiencing ejaculatory dysfunction, 16 (24.2%) had concerns but continued therapy, and 4 (6.0%; 95% CI: 2.4–14.6%) discontinued due to sexual side effects. The overall continuation rate among those affected was 89.3%, indicating that most men tolerated or accepted ejaculatory changes in favor of urinary

symptom relief. The discontinuation rate, though low, reflects a clinically meaningful subset with unacceptable side-effect burden.

**Table V:** Drug continuation status among the study population (n=66)

Drug continuation Status	Number of patients	Percentage (%)
Continued despite side effects	43	65.1
Had concerns but continued	16	24.2
Discontinued due to side effects	4	6.0
Continued, had no side effects	3	4.5
Total	66	100



**Figure 5:** Pie chart showing Drug continuation status

## Discussion

The clinical benefit of Silodosin in lower urinary tract symptoms (LUTS) arises from potent  $\alpha 1A$ -mediated relaxation of prostatic and bladder-neck smooth muscle, reducing outlet resistance and improving urinary flow and symptom scores<sup>4,5</sup>. However, this receptor

selectivity also affects structures involved in emission of semen, including the vas deferens, seminal vesicles, and ejaculatory ducts, leading to a predictable increase in ejaculatory disturbances<sup>10,11</sup>.

In our series, anejaculation occurred in 22.7% of men, while 72.7% reported reduced



ejaculate volume. These rates align with prior studies: Chapple et al. and Schilit et al. reported abnormal ejaculation in roughly 28% of silodosin recipients<sup>5,8</sup>, whereas Sertkaya et al. documented 22.3% among Japanese patients<sup>7</sup>. Thus, our findings support the concept that ejaculatory effects are pharmacologically driven and observed across populations, rather than being population-specific.

The predominance of reduced ejaculate volume over complete anejaculation suggests a partial impairment of seminal emission in most patients. Mechanistically,  $\alpha 1A$ -adreno receptor blockade diminishes contraction of the vas deferens and seminal vesicles during the emission phase, while preserving orgasmic sensation and erectile function<sup>10,11</sup>. Roehrborn et al., via video urodynamics, demonstrated attenuated antegrade semen propulsion under silodosin, corroborating the clinical pattern observed<sup>10</sup>. Similarly, Hayashi et al. confirmed reduced seminal vesicle contractility when exposed to silodosin, reinforcing the physiological mechanism for volume reduction<sup>11</sup>.

Despite the high prevalence of ejaculatory alterations, treatment adherence remained strong in our cohort: around 90% continued therapy, and only 6% discontinued due to sexual side effects. Comparable continuation rates have been reported in post-marketing surveillance from Japan and Europe, where discontinuations for sexual adverse events rarely exceed 10%<sup>12,13</sup>. Pre-treatment

counselling, informing patients about the likelihood and reversibility of ejaculatory changes, likely contributed to this adherence<sup>7,13</sup>. Importantly, silodosin-related ejaculatory dysfunction is typically reversible upon cessation, with recovery occurring within days to weeks<sup>13</sup>.

The age distribution in our cohort (63.6% aged 55–60 years) indicates that these findings are particularly relevant for middle-aged men who remain sexually active, highlighting the importance of individualized counselling. Older men or those less concerned about fertility may prioritize urinary symptom relief over preservation of ejaculatory function<sup>14,15</sup>.

Interestingly, our results demonstrate that ejaculatory dysfunction does not necessarily lead to treatment discontinuation, emphasizing that men often weigh LUTS improvement against reversible sexual side effects. This underscores the importance of shared decision-making and informed consent in routine urological practice<sup>6,12,13</sup>.

Finally, when compared with other  $\alpha 1$ -blockers such as tamsulosin and alfuzosin, Silodosin with greater  $\alpha 1A$  selectivity results in more pronounced LUTS improvement but a higher incidence of ejaculatory effects. Network meta-analyses corroborate this trade-off between efficacy and sexual adverse effects, emphasizing the need for individualized therapy selection, particularly for sexually active men<sup>14-16</sup>.

### **Clinical implications**

**Proactive counselling:** To discuss probable ejaculatory changes before initiation to set expectations and reduce anxiety.

**Reassurance on reversibility:** To emphasize that, effects typically resolve after discontinuation.

**Individualized prescribing:** To prioritize LUTS relief in older men; consider alternative agents in younger men or those wishing to preserve fertility.

Overall, the 22.7% anejaculation rate observed aligns with global experience, confirming that ejaculatory effects of Silodosin are a predictable pharmacological phenomenon. With structured counselling and individualized treatment decisions, Silodosin remains an effective and generally well-tolerated option for BPH.

### **Conclusion**

Silodosin 8 mg once daily, effectively improves lower urinary tract symptoms in men with BPH, with anejaculation occurring in

22.7% and reduced ejaculate volume predominating, indicating mostly partial impairment of seminal emission with preserved orgasm. Most patients continued therapy when properly counselled, reflecting good tolerability and adherence.

These results highlight the importance of proactive counselling, reassurance about reversibility, and individualized therapy, especially in sexually active men or those prioritizing fertility. Shared decision-making, balancing symptom relief and potential ejaculatory changes, is key to optimizing adherence.

### **Further scope of the study**

Future research should explore long-term outcomes, the reversibility timeline of ejaculatory changes, and direct comparisons with other  $\alpha 1A$ -selective adrenoreceptor blockers to refine evidence-based, patient-centred management strategies for BPH.

**Conflict of Interest:** The authors declare that there is no conflict of interest regarding this study.

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### **Authors Contribution**

Work Concept and design 1,2,3

Data collection and analysis 2

Responsibility for statistical analysis 2

Writing the article 1,2,3

Critical review, 1, 2,3

Final approval of the article 1,2,3

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