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## Expert opinion on the prescription practice of paroxetine for the treatment of anxiety disorders in Indian settings

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### Abstract

**Objective;** To gather expert opinion regarding prescription practices and management strategies for anxiety disorders with a special focus on paroxetine among clinicians in Indian settings.

**Methodology:** The cross-sectional study utilized a 19-item, multiple-response questionnaire to gather expert opinions from specialists in managing anxiety disorders. The survey encompassed questions about current prescription practices, clinical observations, preferences, and experiences related to managing anxiety disorders in routine settings. Descriptive statistics were used to analyze the data.

**Results:** This study included 414 experts, with a significant proportion (92.51%) reporting that the selective serotonin reuptake inhibitors (SSRIs) class of anxiolytics manage well for patients with generalized anxiety disorder. Nearly half (50.48%) of the participants reported paroxetine as the most effective SSRI for managing generalized anxiety disorder. Sexual disturbances were reported by 51% of clinicians as the most common side effect of paroxetine leading to discontinuation or switching to another drug. More than half (68.6%) of the clinicians indicated depression as the most common comorbidity associated with anxiety disorder. About 89% of clinicians stated that combining a benzodiazepine with an SSRI during the first week of treatment was necessary. According to 81% of the participants, there was a strong positive association between early responders and achieving full remission. As indicated by 40% of the experts, the most common reasons for patients switching from other SSRIs to paroxetine were adverse effects and lack of efficacy. As reported by 48% and 47% of the clinicians, respectively, the preferred doses for paroxetine in treating anxiety disorder were 25 mg and 12.5 mg.

**Conclusion:** The survey findings indicated that SSRIs, particularly paroxetine, were preferred for treating generalized anxiety disorder in Indian settings. Depression was frequently comorbid with anxiety disorders, and combining benzodiazepines with SSRIs was commonly practiced during the initial treatment phase.

**Keywords:** Anxiety disorder, paroxetine, selective serotonin reuptake inhibitors, depression, benzodiazepines

### Introduction

Anxiety disorders are the most common psychiatric conditions and a major source of disability. They impose a substantial burden on individuals, affecting daily functioning and overall well-being<sup>[1,2]</sup>. Globally, an estimated 4% of the population currently experiences an anxiety disorder. In 2019, anxiety disorders affected 301 million people worldwide, making them the most prevalent mental disorders. Women are more frequently affected by anxiety disorders than men, with symptoms often beginning in childhood or adolescence<sup>[3]</sup>. In 2020, the number of individuals living with anxiety and depressive disorders rose significantly due to the COVID-19 pandemic, with initial estimates showing a 26% and 28% increase respectively for anxiety and major depressive disorders in just one year<sup>[4]</sup>.

In India, one in seven individuals suffers from a mental health disorder like anxiety and depression. The National Mental Health Survey (NMHS), conducted in 2015-16, reported that almost 15% of the Indian population requires active intervention for one or more mental health issues. The survey estimated that about 3.5% of India's population suffers from some form of stress or anxiety-related disorder. A study published in 2017 estimated that almost 197 million individuals in India had mental health disorders, with depression affecting 45.9 million individuals and anxiety impacting 44.9 million (3.3% of India's population)<sup>[5]</sup>.

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Despite the availability of highly effective treatments, only about 1 in 4 individuals with anxiety disorders receive treatment [3]. Selective serotonin reuptake inhibitors (SSRIs) are considered the first-line treatment for anxiety and related disorders, including panic disorder, generalized anxiety disorder, social anxiety disorder, and specific phobias. They are preferred due to their favorable risk-benefit ratio. SSRIs are widely prescribed because of their safety, efficacy, and tolerability, and they are approved for use in both adults and children [1, 6, 7].

Paroxetine, an SSRI approved by the Food and Drug Administration (FDA) for treating anxiety and related disorders, acts by blocking the serotonin reuptake transporter (SERT), thereby increasing the concentration of synaptic serotonin. It is believed that a reduced serotonin concentration in a depressed brain leads to the upregulation of serotonergic receptors. By increasing synaptic serotonin levels, paroxetine causes the downregulation of these previously upregulated receptors, normalizing their concentration. In addition to being a serotonin reuptake inhibitor, paroxetine also exhibits mild to moderate noradrenergic effects by inhibiting the reuptake of norepinephrine, which can help alleviate lethargy in depressed patients [8]. Current evidence shows that the safety and tolerability of paroxetine are comparable to those of other SSRIs and newer antidepressants [9]. Paroxetine is equally bioavailable from oral suspension and tablets. It is completely absorbed and distributed throughout the body, including the central nervous system, with only 1% remaining in the plasma [10].

This study aims to collect expert insights on the prescribing preferences and practices regarding paroxetine for managing anxiety disorders in Indian clinical settings, potentially guiding clinicians in optimizing treatment strategies and improving patient outcomes.

**Methodology**

A cross sectional, multiple-response questionnaire based survey among psychiatrists in the major Indian cities from June 2023 to December 2023.

**Questionnaire**

The questionnaire booklet titled PACE (PARoxetine effiCacy and tolerability profile) study was sent to the psychiatrists who were interested to participate. The PACE study questionnaire consisted of 414 questions that comprised 19 questions aimed at gathering feedback, clinical observations, and experiences from specialists regarding the treatment of anxiety disorder, with a specific focus on the use of paroxetine in routine settings. The questions were designed to gather insights into the frequency of use, perceived efficacy, adverse effects, and preferences for specific combinations. The study was performed after obtaining approval from Bangalore Ethics, an Independent Ethics Committee which was recognized by the Indian Regulatory Authority, Drug Controller General of India.

**Participants**

An invitation was sent to psychiatrists across India based on their expertise and experience in treating anxiety and depression in the month of March 2023 for participation in this Indian survey. About 414 clinicians from major cities of all Indian states representing the geographical distribution

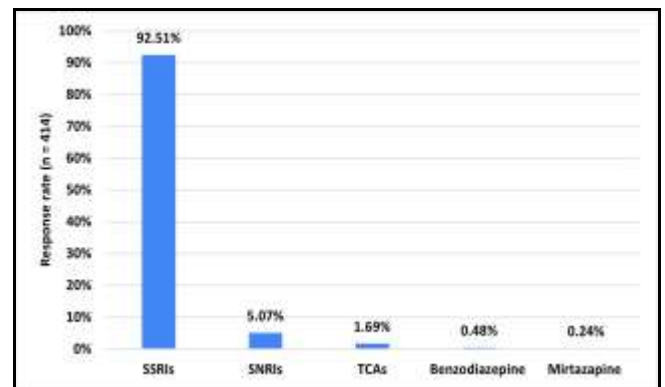
shared their willingness to participate and provide necessary data. The questionnaire was completed independently by the clinicians without consulting their peers, and each doctor provided written informed consent prior to the study's implementation.

**Statistical Methods**

The data was analyzed using descriptive statistics. Categorical variables were presented as percentages to provide clarity on their distribution. The frequency of occurrence and the corresponding percentage were used to represent the distribution of each variable. Graphs and pie charts were created using Microsoft Excel 2013 (version 16.0.13901.20400) to visualize the distribution of the categorical variables.

**Results**

The study included 414 participants, among which 58% of them opined that around 10 to 20 patients show symptoms of anxiety daily in their clinical practice. As reported by 45% of the clinicians, the most common symptom in patients with anxiety disorder was panic attacks. Majority (62.8%) of the clinicians indicated that both pharmacotherapy and non-pharmacotherapy form of treatments manage well for patients with anxiety. A significant proportion (92.51%) of the participants reported that the SSRIs class of anxiolytic works well for patients with generalized anxiety disorder (Figure 1).



**Fig 1.** Distribution of response to the efficacy of different classes of anxiolytics in patients with generalized anxiety disorder

According to half (50.48%) of the participants, paroxetine was the most effective treatment for generalized anxiety disorder (Table 1). Additionally, 42% of clinicians reported that approximately 25 to 50% of individuals show improvement after receiving paroxetine for generalized anxiety disorders. Around 51% of the experts identified sexual disturbances as the most common side effect of paroxetine, leading to discontinuation or switching to another medication (Table 2).

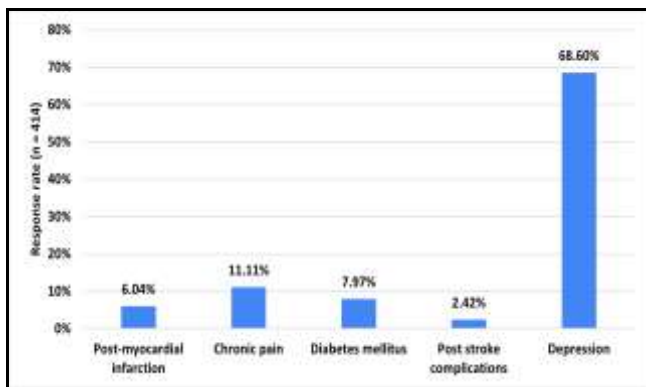
**Table 1:** Distribution of response to the efficacy of medications in generalized anxiety disorder

Medications	Response rate (n = 414)
Escitalopram	30.19%
Paroxetine	50.48%
Sertraline	3.14%
Clonazepam	13.29%
Alprazolam	1.69%
Etizolam	1.21%

**Table 2:** Distribution of response to the most common adverse effects of paroxetine that results in discontinuation/switching to another drug

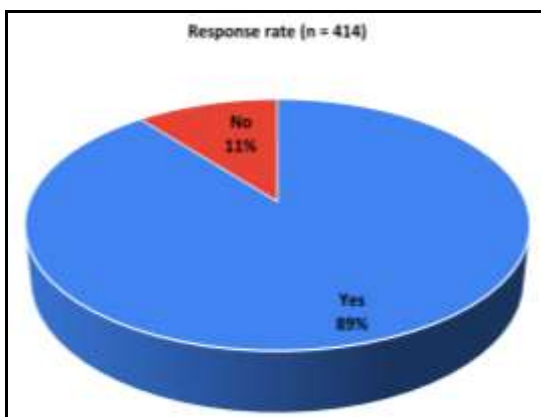
Adverse effects	Response rate (n = 414)
Sexual disturbance	51.21%
Insomnia	15.94%
Dry mouth	19.08%
Loss of appetite	12.32%
Others	1.44%

More than half (68.6%) of the clinicians indicated depression as the most common comorbidity associated with anxiety disorder (Figure 2). As reported by 50% of the clinicians, about 21 to 40% of the patients suffer from anxiety disorders associated with depression. About 50% of the participants reported that 12 weeks was the average time for a patient on paroxetine to achieve remission while 45% of them reported that 8 weeks was the time for remission.



**Fig 2:** Distribution of response to the most common comorbidities associated with anxiety disorder

About 89% of clinicians believed that combining a benzodiazepine with an SSRI during the first week of treatment was necessary (Figure 3). As reported by 93% of the respondents, clonazepam was the preferred choice of benzodiazepine. Paroxetine would be useful in both obsessive-compulsive and panic disorders as reported by 31% and 24% of the clinicians respectively. According to 81% of the participants, there was a strong positive association between early responders and achieving full remission (Table 3). Nearly 52% of the clinicians stated that <10% of the patients failed to respond to the initial therapy for anxiety disorder.

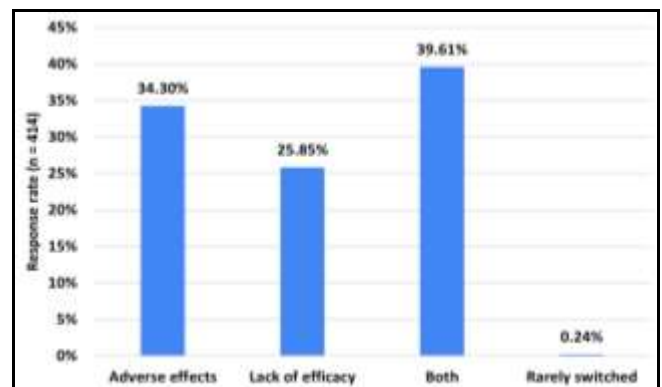


**Fig 3:** Distribution of response to the need to combine benzodiazepine with SSRI during the initial week of anxiety disorder treatment

**Table 3:** Distribution of response to the association between early response and achieving full remission

Association	Response rate (n = 414)
Strong	80.68%
Weak	12.56%
No association	6.76%

According to 40% of the participants, the most common reasons for patients switching from other SSRIs to paroxetine were adverse effects and lack of efficacy (Figure 4). Additionally, 45% of participants reported that dose escalation was the preferred strategy for patients who do not respond to initial treatment with paroxetine. Nearly half (50.72%) of the participants believe that improving patient awareness and counseling can help limit the dropout rate in the management of anxiety disorders. Furthermore, 48% and 47% of clinicians indicated that the preferred doses of paroxetine for treating anxiety disorders were 25 mg and 12.5 mg, respectively (Table 4).



**Fig 4:** Distribution of response to the most common cause of patients switching from other SSRIs to paroxetine

**Table 4:** Distribution of response to the preferred dose for paroxetine in anxiety disorder

Dose (mg)	Response rate (n = 414)
12.5	46.86%
25	48.31%
37.5	4.83%

**Discussion**

The study findings underline the necessity for clinicians to adopt a multifaceted approach in the management of anxiety disorders, incorporating both pharmacological and non-pharmacological strategies tailored to individual patient needs. According to the survey, SSRIs class of anxiolytic was ideal for patients with generalized anxiety disorder. Supporting this, Strawn *et al.* reported that SSRIs are effective in alleviating symptoms of generalized anxiety disorder and are recognized as first-line therapy for long-term management [11]. Similarly, Gautam *et al.* identified SSRIs as the preferred treatment option for generalized anxiety disorder [6]. Furthermore, Baldwin *et al.* conducted a meta-analysis of various SSRIs, confirming their efficacy in reducing anxiety symptoms [12].

As per the majority of survey respondents, paroxetine was most effective for generalized anxiety disorder. Consistent with this finding, Rickels *et al.* showed that paroxetine was an effective and well-tolerated treatment for generalized anxiety disorder. Patients receiving paroxetine experienced greater reductions in anxiety symptoms and disability



compared to those receiving placebo [13]. Pollack *et al.* evaluated the efficacy of paroxetine in the treatment of generalized anxiety disorder and found that it was effective in reducing both the severity and frequency of anxiety symptoms [14].

The present study results shown that the most common side effect of paroxetine that results in quitting or switching over to another drug was a sexual disturbance. In line with this, Montejo *et al.* investigated the prevalence of sexual dysfunction during treatment with different SSRIs and found that paroxetine has one of the highest rates (70.7%) of sexual side effects, often leading to patients discontinuing or switching therapies. In comparison, men reported a slightly higher frequency of sexual dysfunction compared to women (62% and 60% respectively) [15]. Studies have stated that paroxetine was associated with several sexual side effects. In men, it poses a significant risk for delayed ejaculation, reduced desire, impotence, decreased libido, inability to reach orgasm, erectile dysfunction, and abnormal ejaculation. In women, it can cause delayed or absent orgasm and inadequate lubrication [16-18].

More than half of the clinicians surveyed indicated that depression was the most common comorbidity associated with anxiety disorder. In clinical practice, it was common to see depressive disorders accompanied by significant anxiety symptoms or an anxiety disorder. Studies indicated that over 70% of individuals with depressive disorders also experience anxiety symptoms, and 40 to 70% meet the criteria for at least one anxiety disorder concurrently. [19-21]

Kessler *et al.* found that a significant number of individuals with anxiety disorders also had major depressive disorders. They identified that most of the patients with generalized anxiety disorder also had depression, and the rate was even higher for other anxiety disorders such as panic disorder and social anxiety disorder. The study emphasized the significant overlap between these two conditions and suggested that treatment plans for anxiety disorders should also consider potential depressive symptoms [22]. Kalin *et al.* indicated that anxiety and depressive disorders were among the most common psychiatric illnesses. They were highly comorbid with each other and together they were considered to belong to the broader category of internalizing disorders [23].

Studies have shown that the combination of benzodiazepine with an SSRI during the initial phase of treatment can provide several significant benefits to patients. It allows for more rapid control of anxiety symptoms, which was crucial given the delayed onset of SSRIs. This combination can help mitigate SSRI-induced anxiety or agitation, which can occur early in the course of therapy and potentially discourage patients from continuing their medication. This approach can improve adherence to antidepressant therapy. The use of benzodiazepines can offer better control of episodic or situational anxiety that arises in response to specific stimuli, enhancing overall treatment effectiveness. Benzodiazepines are often used in combination with SSRIs during the first few weeks of treatment before the antidepressants reach their full therapeutic potential and the combined treatment with paroxetine and clonazepam resulted in a more rapid response compared to SSRI monotherapy. This evidence aligns with the current survey results [24-26].

The current study results showed that there was a strong positive association between early responders and achieving full remission. Henkel *et al.* demonstrated that early improvement in depressive symptoms within the first two weeks of treatment strongly predicts later response and remission. This emphasized the importance of monitoring early changes to predict long-term outcomes in treating depression [27]. A meta-analysis conducted by Szegegi *et al.* among several clinical trials confirmed that early improvement (within the first two weeks) was a strong predictor of later remission in patients undergoing antidepressant treatment. The study concluded that early response could be a valuable clinical tool for guiding treatment decisions [28].

According to the present survey, the most common reasons for patients switching from other SSRIs to paroxetine are both adverse effects and lack of efficacy. A study by Montgomery SA highlighted that paroxetine was often associated with a higher incidence of side effects compared to other SSRIs. Side effects such as sexual dysfunction and weight gain may contribute to patients switching medications [29]. A meta-analysis by Serretti and Chiesa explored the sexual side effects associated with SSRIs. Paroxetine was noted for its higher risk of sexual dysfunction compared to other SSRIs, which may lead patients to switch medications [30]. Cipriani *et al.* provided evidence on the comparative efficacy of SSRIs. It shown that paroxetine was often less effective compared to some other SSRIs [31].

Rickel *et al.* demonstrated that paroxetine at doses of 20-40 mg/day was effective for many patients with generalized anxiety disorder supporting the use of lower doses as viable treatment options. This aligns with the current survey results suggesting 25 mg as a preferred dose [13]. Similarly, Shrestha *et al.* recommended a starting dose of paroxetine at 12.5 mg orally once daily, with increments of 12.5 mg at weekly intervals, emphasizing a cautious dose escalation approach that was often employed in clinical practice. [10] Pollack *et al.* reported that doses of paroxetine ranging from 20 to 50 mg once daily were effective in treating generalized anxiety disorder. They observed improvements in core symptoms and significant reductions in disability within 8 weeks of treatment. This further supported the effectiveness of doses around 25 mg and highlighted the therapeutic window for paroxetine in managing anxiety disorders [14]. This supported the present survey findings, emphasizing the effectiveness of 25 mg and 12.5 mg doses of paroxetine as preferred options for managing anxiety disorders.

The survey findings can guide clinicians in optimizing treatment strategies for anxiety disorders, considering both the benefits and potential drawbacks of medications like paroxetine. The major strengths of this survey are its larger sample size and the use of a well-designed and validated questionnaire, which ensures robust data collection and reliable insights from practitioners. However, it is important to acknowledge that personal perspectives could have influenced the conclusions, and the reliance on expert judgments increases the likelihood of bias. Therefore, it is essential to interpret the results with these limitations in mind. Further research is necessary to validate these findings and explore strategies to mitigate side effects and improve treatment adherence.

## Conclusion

This study highlighted that paroxetine was considered the most effective SSRI for treating generalized anxiety disorder, despite its common side effect of sexual disturbances. Both pharmacotherapy and non-pharmacotherapy were deemed effective for anxiety treatment. Additionally, combining a benzodiazepine with an SSRI during the initial week was widely recommended.

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## Conflict of Interest

Not available

## Financial Support

Not available

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