International Journal of Science and Healthcare Research
[Indexed, Peer-Reviewed Journal]
Vol. 11; Issue: 1; Jan.-March 2026
Website: ijshr.com
Original Research Article *ISSN: 2455-7587*

Prescribing Pattern in Patients with Parkinsonism Attending Out-Patient Clinic in Tertiary Care Centre in North India

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DOI: https://doi.org/10.52403/ijshr.20260126

ABSTRACT

Introduction: Parkinson's disease (PD) is a common neurodegenerative disorder with variable prevalence across India. Management typically involves Levodopa, but long-term use can lead to complications. This study examines prescribing patterns for PD patients in a tertiary care center in North India, aiming to estimate the proportion of patients on Levodopa (100/25) and describe the adverse effects of anti-parkinsonian therapy.

Materials and Methods: A 12-month cross-sectional study enrolled 100 PD patients, classified as Idiopathic/Typical Parkinson's Disease (IPD) or Atypical PD based on clinical assessments. Medication regimens were reviewed, and patients were followed up three months post-consultation to monitor health status and Adverse Drug Reactions (ADRs). Statistical analyses were conducted using t-tests and Chi-square, with significance set at $p \leq 0.05$.

Results: 84% of patients were diagnosed with IPD and 16% with atypical PD. Levodopa was the most commonly prescribed medication (83%), with significant differences in usage between IPD and atypical PD. Dopamine agonists were exclusively used in IPD patients. Common ADRs included nausea, dizziness, and headaches, mainly associated with Levodopa. Medication compliance was high (90%), though side effects and costs posed challenges.

Discussion: The study highlights the predominance of IPD and the extensive use of Levodopa in PD management in North India. Early diagnosis and tailored treatment are crucial, particularly in resource-limited settings. Managing ADRs is essential for optimizing patient outcomes.

Conclusion: This study provides critical insights into PD management in North India, emphasising the importance of early diagnosis, personalized treatment, and ADR monitoring to enhance patient quality of life and adherence.

Keywords: Parkinson's disease, Levodopa, Adverse drug reactions

BACKGROUND

Parkinson's disease (PD) ranks as the second most prevalent neurodegenerative disease after Alzheimer's disease.[1] It was first comprehensively described by James Parkinson in 1817 in his essay "An Essay on the Shaking Palsy," where he identified and

documented six cases of the disorder. Later, in the late 19th century, Jean-Martin Charcot refined the clinical description of the disease and renamed it PD.[2] In the 1950s, Swedish scientist Arvid Carlsson discovered that dopamine deficiency in the substantia nigra is a core feature of PD.[3] This discovery led to the development of levodopa therapy, which was first used successfully by George Cotzias and colleagues in the late 1960s to treat PD symptoms.[4]

Globally, PD affects around 1% of adults over the age of 65, with its prevalence expected to increase as populations age.[5] In India, rates vary significantly, from lower prevalence in rural areas like Kashmir (14/100,000) to higher rates among communities such as the Parsis in Mumbai (192/100,000).[6]

PD is primarily characterized by four motor symptoms: tremor at rest, rigidity, bradykinesia, and postural instability, which worsen over time and affect quality of life. In addition to motor symptoms, non-motor symptoms like mood disorders, constipation, sleep disturbances, and autonomic dysfunction also commonly occur, often preceding motor symptoms and adding to the disease's complexity.[7]

Drug management of PD aims to alleviate symptoms and enhance quality of life. Levodopa, a precursor to dopamine, is the most effective treatment, replenishing depleted dopamine levels in the brain.[8] However, long-term use can lead to complications like dyskinesias and motor fluctuations, requiring additional medications to manage these side effects. Dopamine agonists (DAs), which directly stimulate dopamine receptors, are often used as an alternative or adjunct to levodopa, especially in younger patients.[9] Other treatment options include Monoamine Oxidase-B (MAO-B) inhibitors, which help preserve existing dopamine, and Catechol-O-methyl transferase (COMT) inhibitors, which prolong the action of levodopa. Anticholinergic drugs and amantadine are also used, although they are typically reserved for specific symptoms.[10]

Currently, there are no specific guidelines in the therapeutic algorithm for PD, leading to variations in treatment approaches. Patients may be prescribed levodopa and other aforementioned drugs either as single agents or in combination. The balance between the effectiveness of a drug and its side effect profile is a major determinant in the drugs prescribed by neurologists and movement disorder specialists.

In our country, where accessibility to deep brain stimulation (DBS) is limited due to cost and logistic issues, it becomes paramount to have a thorough understanding of the pharmacodynamic profile of the drugs, as these medications need to be administered for a long term. Hence, in this study, we sought to assess the drug prescribing pattern in patients with PD and Atypical Parkinsonism and to study the side effects of these drugs in PD patients.

METHODOLOGY

This cross-sectional, observational study was conducted over a period of 12 months in a tertiary care centre in North India. A total of 100 consecutive parkinsonism patients aged 18 years or older attending the outpatient department were enrolled in the study. Patients with parkinsonism secondary to drugs, trauma or metabolic dysfunction were excluded. Pregnant or lactating women, patients on dopaminergic agents for non-PD reasons such as restless leg syndrome were excluded as well.

The clinical diagnosis of PD was made as per the MDS-UPDRS criteria. Likewise, patients were classified as Progressive Supranuclear Palsy (PSP), Multiple System Atrophy (MSA) or Corticobasal Syndrome (CBS) based on a combination of clinical assessments, laboratory tests, and neuroimaging findings.[11]

Patients were grouped as Idiopathic/Typical PD (IPD) and Atypical PD. The atypical PD group was further classified as PSP, MSA and CBS. Initial patient assessments involved reviewing prior medical records and documenting prescribed medications to understand treatment patterns and history.

Patients were further categorised based on their medication regimen (Levodopa alone or in combination) and disease duration (Early <5 years or Late >5 years PD). Each patient was seen and evaluated by a neurologist and changes made in the drug prescription were recorded. These patients were then reassessed three months after their initial visit. This follow-up involved out-patient visits, telephonic conversations, or interviews with relatives to inquire about the patient's health status and any adverse drug reactions (ADRs) to anti-PD medications. Detailed records of medication dosages and any ADRs experienced during or after treatment cessation were maintained. The onset and duration of ADRs were carefully recorded, along with any measures taken to alleviate these reactions. The three-month follow-up was chosen as it aligns with routine clinic appointments, allowing for consistent monitoring and evaluation of treatment outcomes.

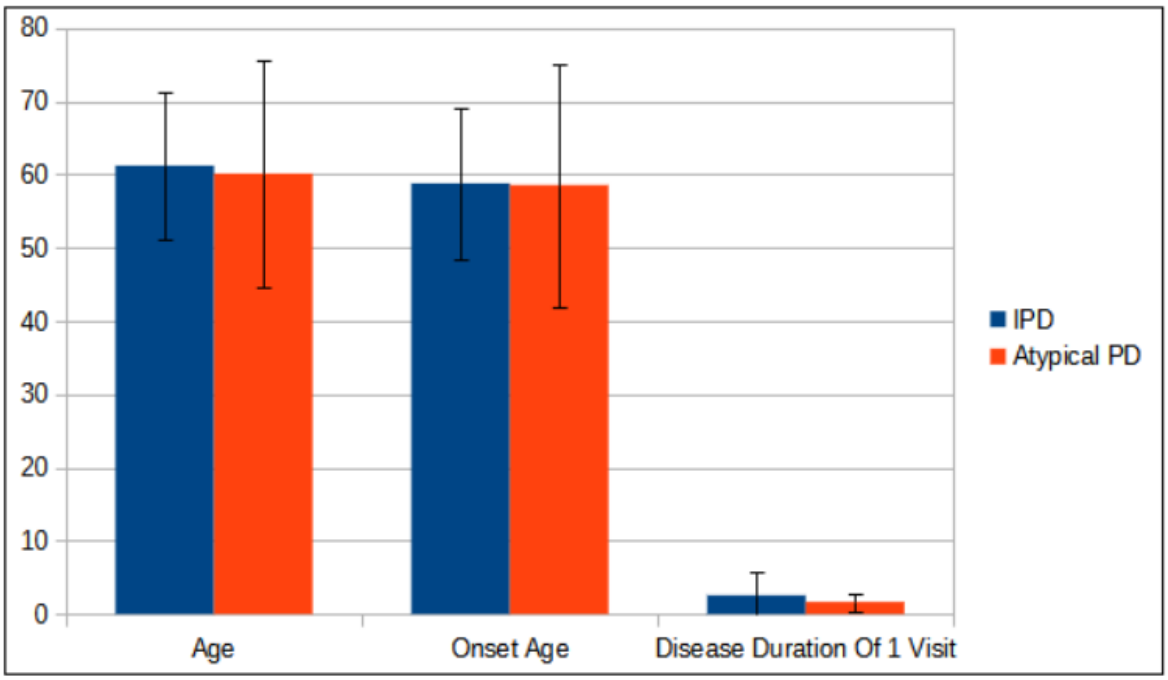
Data on patient demographics (age, sex, and study date) and clinical notes were documented and entered into a Microsoft Excel sheet. The data were then analysed using SPSS software version 21.0. Descriptive analysis was used to summarise categorical data in terms of mean ± standard deviation, median (range), and frequency. Student t-tests for continuous variables and Chi-square tests for categorical variables were employed to compare groups based on gender and age. A p-value of ≤ 0.05 was considered statistically significant.

The study was approved by the institutional ethics committee (IEC No. 117/22).

RESULTS

Out of 100 PD patients enrolled, 84% were diagnosed with IPD and 16% with Atypical PD, including conditions like PSP, MSA, and CBS. No other diagnoses were observed in the study. Study shows male predominance in both groups. The mean age and onset age were similar between the groups, but IPD patients had a significantly longer disease duration at the first visit to our tertiary care centre (2.56 years) compared to Atypical PD patients (1.65 years) (Fig 1). Symptoms at onset of disease and asymmetry were significantly more common in IPD. The UPDRS scores, assessing disease severity, were similar between the two groups. (Table 1)

Figure 1. Comparison of Age, Onset Age and Disease duration at 1st visit between IPD & Atypical PD cases



This bar chart compares the average age, age at disease onset, and disease duration at the first visit between patients with Idiopathic Parkinson's Disease (IPD) and Atypical Parkinson's Disease (PD). The blue bars represent IPD cases, while the orange bars represent atypical PD cases.

Age: The bars indicate that the average age of patients in both groups is similar, with IPD patients slightly younger on average than atypical PD patients. The error bars represent the standard deviation, showing the variation in age among patients in each group.

Onset Age: The age at disease onset is also comparable between the two groups, with IPD patients having a slightly lower average onset age. Again, the error bars represent the standard deviation, highlighting the variability in onset age.

Disease Duration at First Visit: The duration of the disease at the first visit is shorter in atypical PD cases compared to IPD cases. The error bars show less variability in this parameter, indicating that most patients had a similar disease duration at the time of their first visit.

The figure visually demonstrates that while age and onset age are similar between the two groups, IPD patients tend to have a longer disease duration by the time of their first visit, compared to atypical PD patients.

Table 1. Demographic and Clinical characteristics of the patients at baseline.

S. No.	Parameters	Typical/IPD	Atypical PD	p-value
1.	Gender distribution in Parkinson's disease			
	Males	62 (73.8%)	12 (75.0%)	
	Females	22 (26.2%)	4 (25.0%)	
2.	Age- yr	61.21±10.12	60.12±15.55	0.089
3.	Age at onset of disease	58.78±10.34	58.56±16.56	0.987
4.	Disease duration at first visit	2.56±3.12	1.65±1.26	0.012
5.	Symptoms at onset of disease:			
	Tremors	77 (91.7%)	5 (31.3%)	<0.001
	Rigidity	63 (75%)	14 (87.5%)	0.078
	Bradykinesia	64 (76.19%)	9 (56.25%)	0.048
	Gait abnormality	43 (51.2%)	14 (87.5%)	0.012
6.	Asymmetry	80 (95.23%)	7 (43.75%)	<0.001
7.	UPDRS score	26.29±11.89	28.65±14.59	0.485

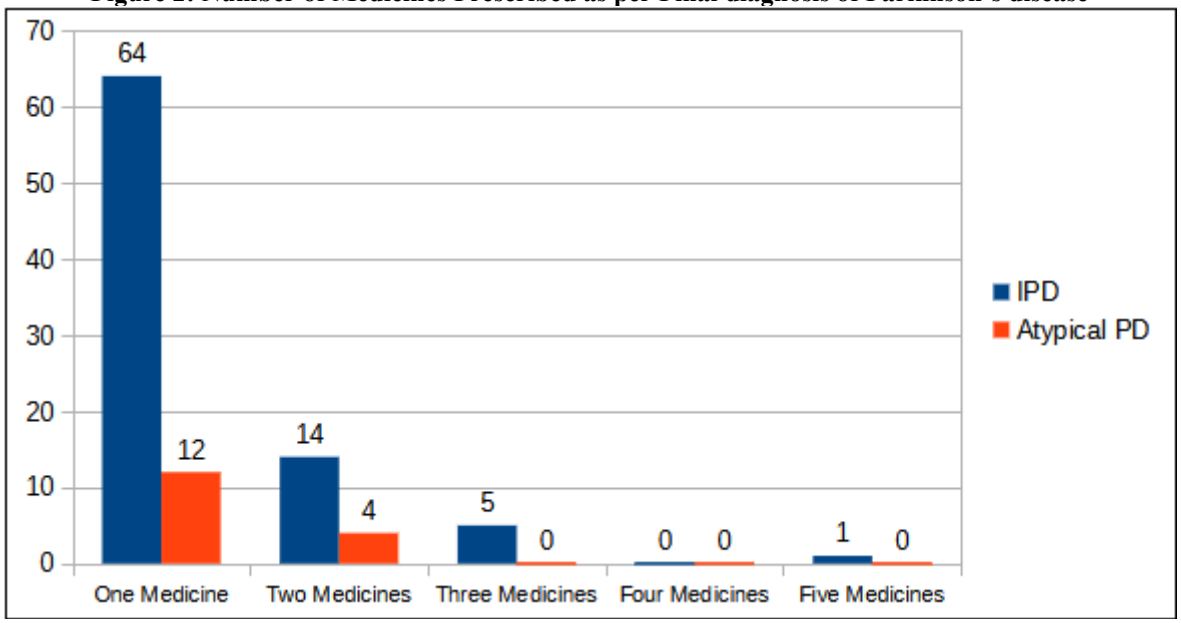
Table 2. Comparison of drug usage between Typical and Atypical PD patients.

S. No.	Parameters		Typical/IPD	Atypical PD	p-value
1.	Final Diagnosis of cases in Parkinson's disease		84 (84%)	16 (16%)	
2.	Comparison of Early vs. Late PD	Early PD	68 (80.95%)	16 (100%)	<0.001
		Late PD	16 (19.05%)	0 (0%)	0.001
3.	Number of Medicines Prescribed	One Medicine	64 (76.2%)	12 (75.0%)	0.072
		Two Medicine	14 (16.7%)	4 (25.0%)	
		Three Medicine	5 (5.6%)	0 (0.0%)	
		Five Medicine	1 (1.2%)	0 (0.0%)	
4.	Levodopa Usage		68 (80.96%)	15 (93.75%)	<0.001
5.	Ropinirole Usage		10 (11.96%)	0 (0.0%)	0.032
6.	Pramipexole Usage		11 (13.9%)	0 (0.0%)	0.041
7.	Amantadine Usage		5 (6.0%)	0 (0.0%)	0.077
8.	THP Usage		15 (17.9%)	3 (18.75%)	0.124
9.	Rasagiline Usage		3 (3.58%)	1 (6.25%)	0.098
10.	Safinamide Usage		1 (1.2%)	0	0.991

Significant differences in prescription patterns were observed between early and late stages of PD patients. Table 2 compares drug usage between IPD and Atypical PD patients. Levodopa was the most commonly prescribed drug, with significant differences in its usage between IPD and atypical PD ($p<0.001$). Ropinirole and Pramipexole were

used exclusively in IPD patients, with no usage in atypical PD, showing significant differences. Most patients in both groups were on a single medication, with no significant difference (Fig 2). ADRs were common, with nausea, dizziness, and headaches being the most frequent, primarily associated with Levodopa (Fig. 3).

Figure 2: Number of Medicines Prescribed as per Final diagnosis of Parkinson's disease



This bar chart illustrates the distribution of the number of medicines prescribed to patients with Idiopathic Parkinson's Disease (IPD) and Atypical Parkinson's Disease (PD). The blue bars represent IPD cases, while the orange bars represent atypical PD cases.

One Medicine: The majority of patients in both groups were prescribed only one medicine, with 64 IPD patients and 12 atypical PD patients falling into this category. This indicates that single-drug therapy is the most common treatment approach for both types of Parkinson's disease.

Two Medicines: A smaller proportion of patients were prescribed two medicines, with 14 IPD patients and 4 atypical PD patients. This shows that combination therapy is less common but still used in both groups.

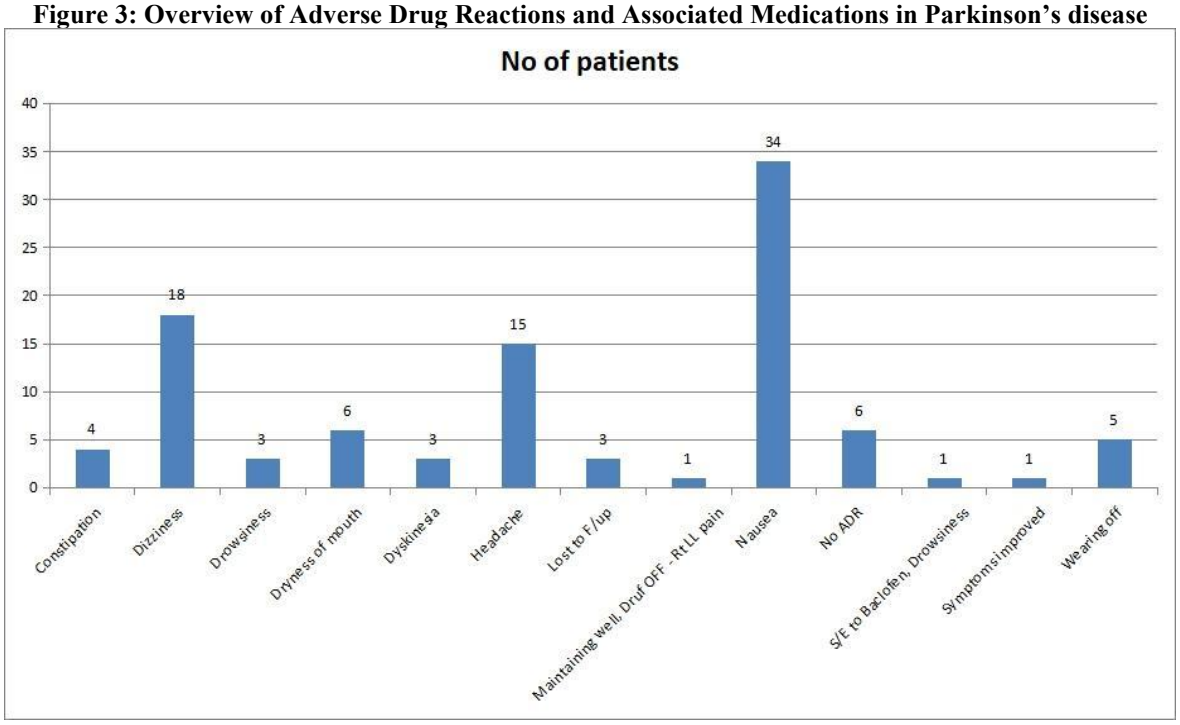
Three Medicines: Only a few IPD patients (5) were prescribed three medicines, while no atypical PD patients were on a three-drug regimen.

Four Medicines: No patients in either group were prescribed four medicines, indicating that this level of polypharmacy is not common in the treatment of Parkinson's disease in this study.

Five Medicines: Only 1 IPD patient was prescribed five medicines, while no atypical PD patients received this many medications, suggesting that such extensive polypharmacy is rare.

This figure highlights that most patients, whether diagnosed with IPD or atypical PD, are managed with a single medication, and the use of multiple medications increases progressively but is less common.

Figure 3: Overview of Adverse Drug Reactions and Associated Medications in Parkinson's disease



This bar chart provides an overview of the different adverse drug reactions (ADRs) experienced by PD patients and the number of patients affected by each reaction. The x-axis lists the various ADRs and related observations, while the y-axis shows the number of patients reporting each issue.

Nausea: The most common ADR, reported by 34 patients, indicating that nausea is a significant side effect of Parkinson's medications.

Dizziness: The second most frequent ADR, with 18 patients experiencing dizziness, highlighting it as another common side effect.

Headache: Reported by 15 patients, making it another notable ADR associated with Parkinson's medications.

Dryness of Mouth: Experienced by 6 patients, showing that this is a moderately common side effect.

Constipation, Drowsiness, Dyskinesia, Lost to F/U, Side Effect to Baclofen/ Drowsiness, and Wearing Off: Each of these reactions or observations was reported by a smaller number of patients, ranging from 1 to 5, indicating they are less common but still relevant.

No ADR: Notably, 6 patients reported no adverse drug reactions, suggesting that some patients tolerate their medications well.

Maintaining Well on Drug Off: Only 1 patient reported maintaining well without medication, while another patient reported improvement in symptoms.

This figure effectively highlights the prevalence and variety of adverse drug reactions among Parkinson's disease patients, with nausea, dizziness, and headache being the most commonly reported.

DISCUSSION

This study examines the prescribing patterns and treatment outcomes among PD patients, including both IPD and atypical cases, in a tertiary care hospital in North India over a 12-month period. PD was more common in males, consistent with prior findings showing men are twice as likely to develop PD.[12] The mean age for both groups was over 60 years, aligning with previous studies indicating higher PD prevalence in elderly population.[13] Most patients (84%) were diagnosed with IPD, and 16% had atypical PD, similar to earlier studies,[14] with no significant difference in age of onset between the groups. However, IPD patients had a

longer disease duration before their first visit, possibly due to the milder symptom profile.

Tremors (82%) were the most common symptom, followed by rigidity (77%), bradykinesia (73%), and gait disturbances (57%) in both idiopathic and atypical PD patients. Tremors are caused by abnormal burst discharges in the subthalamic nucleus, driven by hyperactive inputs from the motor cortex. This disrupts motor rhythms, contributing to tremor and bradykinesia. Rigidity arises from altered brain connectivity, while gait disturbances stem from disruptions in cortico-subcortical loops affecting coordination and stability.[15]

In this study, most patients with asymmetry had IPD, while those without asymmetry were more likely to have Atypical PD, suggesting that asymmetric motor symptoms result from the differential spread of α-synuclein pathology within the CNS.[16] There was no significant difference in motor symptom severity between IPD and atypical PD based on UPDRS scores, potentially due to psychometric limitations of MDS-UPDRS-II and -III, which reduce the precision in early PD symptom assessment.[17] Most IPD cases were in the early stage, typically managed with a single medication like Levodopa.[18] Late-stage patients required more complex treatments, including multiple medications such as DAs, COMT inhibitors, and MAO-B inhibitors to address complications. The shift from single to multiple medications in late-stage PD highlights the need for more intensive therapy as the disease progresses. Early diagnosis and intervention remain crucial, as most IPD and all atypical PD patients sought medical attention in the early stages.

In this study, Levodopa was the most frequently prescribed medication (83%) due to its effectiveness, affordability, and tolerability, especially for older patients.[19] Younger patients, under 60 years of age, often started with DAs like Pramipexole or Ropinirole to delay Levodopa-related motor complications. In contrast, older patients were prescribed Levodopa for immediate symptom relief with a lower risk of dyskinesias.[20] Significant differences were observed in Levodopa usage between IPD and atypical PD patients, with Pramipexole and Ropinirole used exclusively in IPD.

Levodopa remains useful in atypical PD, despite its lower effectiveness, because it controls bradykinetic symptoms when other medications fail. Its safety profile and lack of better alternatives for atypical PD make it a viable option for improving quality of life.[21] Some patients were not prescribed L-dopa due to factors like age, symptom severity, and response to other medications, following established clinical practices and recommendations.

In this study, THP was the second most commonly prescribed drug at 18% with majority patients from the IPD group, because it effectively manages symptoms such as tremors, spasms, stiffness, and weak muscle control. However, these drugs can cause confusion, memory impairment, and hallucinations, particularly in older individuals, potentially worsening cognitive decline. As a result, the use of anticholinergics is generally limited to younger (less than 60 years), cognitively intact patients where the risk of such adverse effects is lower. While they remain effective for managing motor symptoms, their use should be approached with caution, especially in patients who are at greater risk for cognitive issues.[22]

DAs like Ropinirole (10%) and Pramipexole (11%) were prescribed to 21% of patients in the IPD group. After three months, 5 patients (25%) of these patients were switched to Levodopa due to inadequate symptom control or side effects, such as nausea and dizziness. This is consistent with studies showing that 25-30% of patients initially treated with DAs switch to Levodopa for better motor control.[23] Levodopa has been shown to provide superior motor symptom management compared to DAs, which are linked to poorer symptom control and more non-motor side effects.[22,24]

In the study, no significant usage of Rotigotine, Amantadine, Rasagiline, Entacapone, or Safinamide was observed in

both IPD and Atypical PD groups. This aligns with previous study, indicating low usage of COMT inhibitors and MAO-B inhibitors due to concerns over its side effects and limited long-term efficacy.[19,25] Amantadine usage was 6% in this study, compared to 17.2% in a South Indian study, reflecting regional differences possibly due to drug availability, affordability and physician familiarity.[19] THP was prescribed more frequently in this study (40.4%) compared to South India (18%), likely due to its lower cost. Despite these differences, Levodopa remained the most commonly prescribed drug in both regions, with 83% usage in North India compared to 94.8% in South India, suggesting regional variations in early PD management approaches.

Levodopa is often combined with THP to manage tremors and with Amantadine to control dyskinesias in patients with severe motor fluctuations, where Levodopa alone is insufficient.[(28)] It is also paired with Pramipexole or Rasagiline to improve UPDRS scores without raising the risk of adverse events.[26] In this study, patients with symptoms like tremors (82%), rigidity (77%), and bradykinesia (73%) were treated with these combinations, particularly Levodopa with THP or Amantadine in more complex cases, and with Pramipexole or Rasagiline as per disease progression and patient tolerance.

About 40% of patients develop motor fluctuations after 4-6 years of treatment, with this percentage increasing as the therapy continues.[19] After 10 years, nearly 70-80% of patients may experience these fluctuations. Dyskinesias develop in about 30-50% of patients after 5 years of Levodopa treatment, with the prevalence rising to 60-90% after 10 years.[19] In contrast, in this study, 5% of patients discontinued Levodopa due to severe side effects or unmanageable motor complications, such as dyskinesia or motor fluctuations. Approximately 20% of patients developed motor fluctuations, and 12% experienced dyskinesias as a long-term side effect of Levodopa treatment. In these cases, dose fractionation or adjunct therapies like Amantadine and dopamine agonists were employed to mitigate the complications and optimize treatment. However, it is important to note that a 3-month follow-up period is too short to adequately assess the onset of motor fluctuations and dyskinesias, which generally develop after years of Levodopa use.

Physician notes indicated that changes or additions to the drug regimen were typically made to better manage motor fluctuations or inadequate symptom control. DAs like Ropinirole or Pramipexole were added when Levodopa alone was insufficient, while Amantadine was specifically introduced in cases of dyskinesia or tremors. Safinamide was used in a case where motor fluctuations worsened, particularly in late-stage PD, helping to extend the efficacy of Levodopa.

The study provides a detailed overview of ADRs experienced by patients. Nausea was the most common ADR, affecting 34 patients, primarily associated with Levodopa and various drug combinations. Other common ADRs included dizziness (18 patients), headache (15 patients), dry mouth (6 patients), and wearing-off effects (5 patients). Less common side effects like constipation, drowsiness, and dyskinesias were also reported. These findings highlight the importance of careful monitoring and management of ADRs to optimise treatment outcomes and improve patient quality of life.

To combat these side effects, strategies such as adjunctive therapy with carbidopa and domperidone were prescribed to manage nausea. In our study, these medications were found to be effective in mitigating nausea, a finding consistent with similar studies that report their utility in managing dopaminergic therapy-related nausea in PD.[10] Additionally, individualised treatment plans were emphasised to manage non-motor side effects, particularly in elderly patients who are more susceptible to confusion and hallucinations, and other cognitive side effects.

While our management strategies were successful in many cases, some continued to experience side effects like dyskinesias and

wearing-off effects. This is consistent with other research, which shows that ongoing monitoring and adjusting treatments are essential to improve the patient's quality of life.[27] These observations emphasise the need for ongoing vigilance in managing both motor and non-motor side effects, particularly in long-term treatment.

Medication compliance was high at 90%, likely due to effective communication about the illness, the importance of adherence, and regular follow-ups and the good response to Levodopa. However, 10% of patients exhibited poor compliance, often due to side effects, medication costs, and inadequate health education. This highlights the importance of addressing these barriers to improve overall treatment adherence.

The study's strengths include the detailed review of the old records and meticulous note of the drugs prescribed earlier, any new modifications and evaluation at 3 months. Despite the high medication compliance (90%) observed in this study, there are important challenges in managing PD in the community that were not fully explored. While Levodopa was widely prescribed and well-tolerated, many patients experienced significant side effects, which present an ongoing challenge in PD management, especially when considering the long-term nature of treatment. Additionally, 10% of the patients exhibited poor compliance, largely due to side effects, medication costs, and inadequate health education, highlighting the need for better support systems in the community. The lack of established guidelines give the physician a free hand to prescribe and alter drugs and their doses in PD patients. It is crucial for patients to remain under long-term follow-up with consistent adherence to a single physician, rather than engaging in "doctor shopping." In such cases, medication regimens are frequently altered, complicating management at tertiary care referral centers.

Furthermore, the natural history of PD is long, and the three-month follow-up period is too short to fully analyse the effects of drugs in such a chronic, degenerative disease. However, our primary aim was to assess the prescription patterns in PD. It is a remarkable observation that before the first visit to our centre, a high percentage of patients were already on Levodopa, prescribed by their primary physician. This indicates that the illness was not missed in the community, and management, particularly in terms of initiating Levodopa, was largely appropriate. Diagnosing IPD is generally straightforward, but misdiagnosis occurs in 15-24% of cases.[28] Accuracy is around 80.6%, with common errors involving tremor disorders or secondary parkinsonism. Distinguishing Parkinson's from atypical parkinsonian syndromes like MSA, PSP, and CBD is particularly challenging, with error rates ranging from 7-35%.[28]

While short-term management appears adequate, the study primarily focused on prescription patterns, so the complexities of long-term challenges in managing PD, such as side effects and compliance, may not be fully captured within the scope of this analysis. The limited follow-up period restricts our ability to fully capture the complexities of patient care and the long-term effects of drug treatments in the community.

In our study, there were several scenarios where patients were misdiagnosed or not properly treated for PD for extended periods. One such case involved a patient who exhibited classic symptoms of tremors and bradykinesia but was mistakenly diagnosed with essential tremor and went without proper PD medications, such as Levodopa, for several years. Another patient was treated for depression and anxiety, with their motor symptoms attributed to psychiatric causes, leading to a significant delay in receiving PD-specific treatment. This resulted in worsening symptoms and considerable impairment in the patients' quality of life due to delayed initiation of effective therapy.

These scenarios highlight the critical importance of an early visit to physician, particularly a neurologist or a movement disorder specialist, for accurate diagnosis and timely treatment of PD. Early intervention

with appropriate medications, especially Levodopa, can significantly slow the progression of motor symptoms and improve the overall prognosis. It also highlights the need for greater awareness among general practitioners about the early signs of PD to prevent misdiagnosis. Ensuring that patients with suspected PD receive prompt and accurate treatment is crucial in improving long-term outcomes and quality of life for these individuals.

Overall, this study enhances understanding of PD management in Indian context, emphasising the importance of tailored treatment approaches, early diagnosis, and regular monitoring to improve patient outcomes and quality of life. The insights gained can contribute to better management strategies for PD patients.

CONCLUSION

In conclusion, this study provides valuable insights into PD management in North India, focusing on prescribing patterns, treatment outcomes, and medication compliance. It highlights a male predominance in PD cases. The prevalence of Idiopathic PD and the widespread use of Levodopa. The study emphasises the importance of early diagnosis and personalised treatment noting common adverse effects like nausea, dizziness, and headache. High medication compliance was observed, but challenges such as inadequate health education and medication costs were identified.

Declaration by Authors

Ethical Approval: Approved
Acknowledgement: Not Required
Source of Funding: None
Conflict of Interest: The authors declare no conflict of interest.

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How to cite this article Prachi Chauhan, Arpita Singh, Dinkar Kulshreshtha, Shaili Jaiswal, Rakesh Kumar Dixit. Prescribing pattern in patients with Parkinsonism attending out-patient clinic in Tertiary care centre in North India. *Int. J. Sci. Healthc. Res.* 2026; 11(1): 253-263. DOI: *https://doi.org/10.52403/ijshr.20260126*

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