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Original Research Article

Antiparkinson's drug-effects on quality of life and safety among parkinson disease patients- A prospective observational study in a tertiary care hospital of West-Bengal

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ABSTRACT

Introduction: Parkinson's disease (PD) is the second most frequent neurodegenerative disease, affecting 1% of the population aged>60 years due to striatal dopamine deficiency. Dopamine replacement with oral levodopa is the gold standard of symptomatic therapy. Longterm therapy with dopamine agonists might lead to decreased benefit and referred to as 'end of dose deterioration' or 'wearing-off. This leads to decrease quality of life of such patients. There might be safety issues due to longterm use of these drugs. There are few studies conducted in India regarding quality of life studies and safety of antiparkinsonian drugs in Parkinson disease patients and none in West-Bengal. Hence this study is taken up in our tertiary care Hospital.

Aims: To study antiparkinson's drug-effects on quality of life of parkinson disease patients and their safety and tolerability.

Materials and Methods: This prospective, observational study was conducted in Dept of Clinical & Experimental Pharmacology of School of Tropical Medicine Kolkata in collaboration with Departments of Neuromedicine of Kolkata Medical College and Private Clinics of a Neurologist. All Idiopathic Parkinson disease patients from December 2019 to November 2021, were included according to inclusion and exclusion criteria. The study commenced after obtaining approval from institutional ethics committee, and completed in 24 months. Data collected and then statistically analyzed by using WPS Excel and Graph Pad Prism 9 software.

Results: Total Idiopathic Parkinson disease patient were 111 in our study. Anti parkinson drugs were very well tolerated and ADRs were mild in intensity. Antiparkinsonian drugs improve the quality of life significantly.

Conclusion: Antiparkinsonian drugs were well tolerated and safe. Quality of life improved by use of antiparkinsonian drugs in parkinson disease patients.

1. Introduction

Parkinson's disease (PD) is the second most frequent neurodegenerative disease Neuropathological hallmarks are progressive loss of dopaminergic neurons in the

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pars compacta of the substantia nigra, causing striatal dopamine deficiency, and intracellular inclusions containing aggregates of alpha-synuclein.[1,2] PD is clinically defined by the presence of bradykinesia and at least one additional cardinal motor feature (rigidity or rest tremor). In addition, most patients with PD also experience non-motor symptoms (NMS), adding to the overall burden of parkinsonian morbidity.[3–5] PD was the first neurodegenerative disease for which highly efficacious treatments became available. Dopamine replacement with oral levodopa is still the gold standard of symptomatic therapy. The treatment of Parkinson's disease (PD) with dopaminergic therapy, especially in the early stages, is usually associated with significant improvements in motor disability, and the first few years of pharmacotherapy are often referred to as the 'honeymoon period' because patients generally enjoy sustained symptomatic relief with minimal side effects. Satisfactory management of Parkinson's disease is a challenge that requires a tailored approach for each individual. Dopaminergic treatment continues to benefit patients as PD progresses, but within a few years of starting therapy, whether with levodopa alone or levodopa and a dopamine agonist, the majority of patients begin to notice a decline in the duration of benefit of each dose. This is referred to as 'end of dose deterioration' or 'wearing-off.Qualit. Polypharmacy in Parkinsons disease treatment leads to Adverse Drug Reactions which might impair the quality of life.[6–9] Mostly levodopa is used in parkinson disease treatment and addition of other agents like pramipexole, ropinirole, amantadine, trihexyphenydil etc helps in improvement of symptoms and quality of life of patients.[10–13] So safety of antiparkinson's drugs and quality of life effects of antiparkinsonian drugs are important parameter to explore.There are few studies conducted in India regarding safety and quality of life effects of Antiparkinson's drugs in Parkinson disease and none in West-Bengal. Hence this study is taken up in our tertiary care Hospital.

2. Aims & Objectives

To study Antiparkinson's drug-effects on quality of life of parkinson disease patients and their safety and tolerability.

3. Materials and Methods

3.1. Study design

1. Prospective, observational outcomes study.

3.2. Study site

Department of Clinical & Experimental Pharmacology, Calcutta School of Tropical Medicine, Kolkata

3.3. Data collection sites

1. Neurology OPD, Medical College, Kolkata.
2. Private clinic of one Consultant Neurologist in Kolkata/suburb.

3.4. Study period

The study commenced after obtaining approval from institutional ethics committee, and completed in 24 months.

Subject enrolment: 6 months

Follow up: 12 months

Data analysis and report writing: 4 months

Sample size: 111 sample size was found

Study population: All consecutive criteria-eligible, consenting patients attending the

Neurology OPD of Medical College, Kolkata and the private clinic of the one practising Neurologist.

3.5. Inclusion criteria

Adult subjects of either sex, idiopathic parkinsonism (Parkinson's disease) duly diagnosed, attending Neurology Clinic regularly, willing to take part in the study, and having consented, likely to cooperate for periodic follow-up and other protocol-specified formalities were included .

3.6. Exclusion criteria

1. Patients those did not give consent

3.7. Study technique

Patients were enrolled from Neuromedicine OPD of Medical College and Hospital, Kolkata as well as from private clinics of one Neurologist in Howrah, West Bengal according to inclusion and exclusion criteria after taking the informed consent. Patient's data were filled in the Case report form at baseline and then followed up for 3 visits (1month, 3 month and 6 month).The basic demographic details recorded. Quality of life evaluated by Parkinson Disease Questionnaire – 39 at baseline and follow up periods. Safety of antiparkinson medications was analysed by monitoring suspected adverse drug reactions by using Suspected ADR Reporting Form of Indian Pharmacoepia commission (Version 1.3). Causality of such reactions were assessed using WHO UMC Causality Assessment Scale, Naranjo's Algorithm. Severity of the reactions were assessed using Hartwig and Seigel's Severity Assessment Scale.

3.8. Statistical analysis

Data collected and then statistically analyzed.

Descriptive data represented as mean or percentages.

Demographic and categorical data where possible, analyzed with parametric or non-parametric tests using

[Mean± SD, Median, Fisher exact test, Friedman's ANOVA test, Wilcoxon matched pair signed rank test].

Data analysed by using WPS Excel and Graph pad prism 9 software.

3.9. Ethical considerations

The protocol Approved by the Institutional Ethics Committee of School of Tropical Medicine Kolkata(CREC STM/595) & Ethics Committee of Medical college & Hospital Kolkata (MC/KOL/IEC/NON-SPON/771/08/20).

4. Result

Total Idiopathic Parkinson disease patient were 111 in our study

Table 1: Descriptivestatistics of demography

Demography	Age(YR)	Wt(KG)
Mean±sd	61.85±7.20	59.47±6.34
Median	62	59

This Table 1 shows Descriptive statistics of Demography in which mean age was 61.85yr, Median age was 62yr and Mean weight was 59.47kg, Median was 59kg

4.1. Employment status

epicts employment status of Idiopathic parkinson disease patients. A total of 56(50.5%) were found to be in the Unemployed group.

4.2. Comorbidities

epicts Comorbidities among Idiopathic parkinson disease patient. Most common comorbidities were Hypertension 8(33.3%) and Diabetes Melitus type 2 8(33.3%).

Statistical analysis by Friedman's ANOVA shows PDQ39 score was significant in different groups P< 0.001

4.3. Quality of life

epicts quality of life improvement by PDQ 39 score from baseline to subsequent follow ups

4.4. Safety & tolerability

epicts suspected drugscausing ADRs and their causality assessment by WHO-UMC scale and Naranjo causality assessment scale among Idiopathic parkinson disease patients. WHO-UMC Scale AND Naranjo causality assesment scale both revealed 36.4% ADRs were Probable category and 63.6% were possible category.

This table 6 shows Hartwig's severity scale, according to it 11 (100%) ADRs were in level 1 of mild intensity.

The antiparkinson's drugs are well tolerated as having less ADRs.

4.5. Pharmacotherapy

Syndopa found to be most commonly used in parkinson's disease.

Adding dopamine agonists (Ropinirole, Pramipexole), Anticholinergic (Trihexyphenydil), NMDA inhibitors (Amantadine) etc also improve quality of life etc

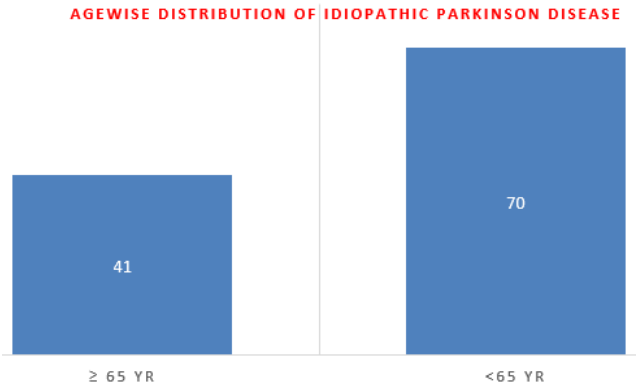

Figure 1: Age wise distribution of idiopathic parkinson disease

This Figure 1 shows age wise distribution of Idiopathic parkinson disease patients.A total of 70(63%) Idiopathic parkinson disease patients were in age group< 65 years and a total of 41(37%) Idiopathic parkinson disease patients were in age group ≥ 65 years.

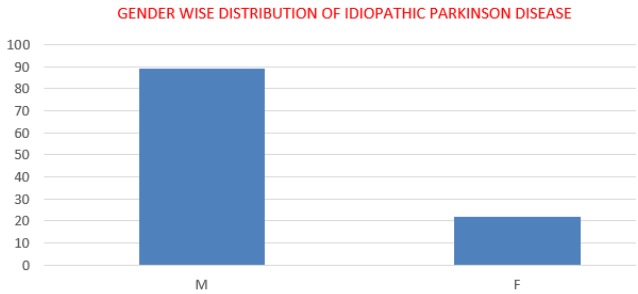

Figure 2: Gender wise distribution of idiopathic parkinson disease

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This Figure 2 shows gender wise distribution of Idiopathic parkinson disease patients.A total of 89(80.2%) Idiopathic parkinson disease patients were found in males and a total of 22(19.8%) Idiopathic parkinson disease patients were found in females

This Table 2 depicts employment status of Idiopathic parkinson disease patients. A total of 56(50.5%) were found to be in the Unemployed group.

This Table 3 depicts Comorbidities among Idiopathic parkinson disease patient. Most common comorbidities were Hypertension 8(33.3%) and Diabetes Melitus type 28(33.3%).

Table 2: Employment status of idiopathic parkinson disease patients

Employed	Unemployed	Self Employed
30(27%)	56(50.5%)	25(22.5%)

Table 3: Comorbidities among idiopathic parkinson disease patients

Hypertension	Diabetes Melitus Type 2	Hypothyroidism	Dyslipidemia	Smoker
8 (33.3%)	8(33.3%)	4(16.7%)	3(12.5%)	1(4.2%)

Total Comorbidities- 24

Table 4: PDQ39 at baseline and follow ups

Score	Baseline (Mean±sd)	1st Follow Up (Mean±sd)	2nd Follow up (Mean±sd)	3rd Follow up (Mean±sd)	Friedman's ANOVA
PDQ 39	180.7±6.35	#183.6±4.65	#188±4.26	#192.3±2.76	P<0.001

#P<0.0001 in comparison to Baseline and (1st, 2nd, 3rd follow up respectively), 1st follow up and (2nd, 3rd follow up respectively), 2nd follow up and 3rd follow up in case of PDQ 39 score.

Table 5: ADRs in idiopathic parkinsonism patients

Suspected Drugs	Adrs	Number of Adrs	Who-Umc Causality Assessment Scale[6,7]	Naranjo Causality Assessment Scale[6,7]
Thp	Dry Mouth	4(36.4%)	Probable	Probable
	Drowsiness	2(18.1%)	Possible	Possible
Syndopa	Dizziness	4(36.4%)	Possible	Possible
Syndopa	Nausea	1(9.1%)	Possible	Possible

Table 6: ADRs according to hartwig's severity scale[6,7]

Severity	Level	Number of ADRs	Total (%)
Mild	1	11	100%
	2	0	
Moderate	3	0	0
	4	0	
Severe	5	0	0
	6	0	
	7	0	

This Table 4 shows Statistical analysis of PDQ39 at baseline and follow ups.

Mean PDQ39 score was 180.7, 183.6, 188, 192.3 at baseline, 1st follow up, 2nd follow up, 3rd follow up respectively.

Statistical analysis by Friedman's ANOVA shows PDQ39 score was significant in different groups P< 0.001.

4.5.1. Total Adrs- 11

This Table 5 depicts suspected drugs causing ADRs and their causality assessment by WHO-UMC scale and Naranjo causality assessment scale among Idiopathic parkinson disease patients. WHO-UMC Scale AND Naranjo causality assesment scale both revealed 36.4% ADRs were Probable category and 63.6% were possible category

This Table 6 shows Hartwig's severity scale, according to it 11 (100%) ADRs were in level 1 of mild intensity.

5. Discussion

Present study was designed to assess safety and tolerability, quality of life in parkinson's disease patients.

5.1. Demographic characteristics of Idiopathic Parkinson disease

Figure 1 shows most of the patients (63%) were in the age group <65 years followed by age group ≥65 years (37%).In our study, mean age found to be 61.85± 7.20 which is nearly corroborated with Shah J et al[14] in that study mean age was 61.88±11.93 and Samii A et al[15] where mean age was 60 yrs.

FIGURE 2 reveals males constituted the majority i.e. 89 of all IPD patient (80.2%) while females comprised 22 cases (19.8%) of IPD patients. In Shah J et al Study[14] ,PD in male : female was 2.007:1 which is similar to our study I.e,M:F -1.7:1

Multiple studies have indicated that male to female ratios for incidence rates vary from 1.37 to 3.7.

5.2. Quality of life

shows distribution of PDQ 39 score among different visits.It also reveals improvement of quality of life from baseline to further follow up visits.

Quality of life is an important measure for parkinson's disease, in terms of physical and mental health outcomes. Quality of life in our study was measured by using PDQ39 Score [16,17].

In our study, we evaluated Quality of life by using PDQ39 questionaire. Mean PDQ39 score was found to be 180.7 at baseline that was found to be improved in follow ups.

In Jugal Saha et al study [14], Mean total PDQ 39 score was 130.45 nearly approximate to our study .Higher the score better is the quality of life.

5.3. Safety & tolerability

Antiparkinson Drugs are usually well tolerated and adverse events range from mild to moderate found in a study by Federico carbone et al.[6] Another study by Thaha F et al[7] also revealed that majority of ADRs in their study were mild in intensity. In our study we assessed safety and tolerability to anti Parkinson's drugs and adverse drug reactions from patients complain, Physical examinations by Neurologists. All the ADRs were mild in intensity as no drug withdrawal or no drug modification needed to treat the ADRs.

5.4. Causality assessment of ADRs by WHO-UMC and Naranjo scales

HO-UMC scale shows7 cases (63.6%) in possible category and 4 cases (36.4%) in probable category, Naranjo scale shows 7 cases (63.6%) in possible category and 4 cases (36.4%) in probable category.

Thaha F et al study[6,7] revealed 72.5% ADRs were found to be possible category and 27.5% were found to be in Unlikely category.

5.5. Severity of Geriatric ADRs by Hart wig's scale

Table 6 Hart wig's scale shows11 cases (100%) were of mild in intensity.

Thaha F et al[6,7] revealed that majority of ADRs in their study were mild in intensity that was nearly similar to our study

6. Limitation

We were able to follow the patients only for 6 months due to the COVID 19 pandemic and associated lockdown all over the country. So, study duration was very short to evaluate the outcomes. Our study was a Time- bound study, so a limited sample size of 111 was collected.

7. Conclusion

Anti Parkinson drugs were very well tolerated and ADRs were mild in intensity.

Anti Parkinson's drugs improve quality of life of Parkinson disease patients

8. Source of Funding

None.

9. Conflict of Interest

None.

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