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Drug-related problems in hospitalised Parkinson's disease patients in China

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ABSTRACT

Background There has been a lack of studies on the types and severity of drug-related problems (DRPs) in hospitalised patients with Parkinson's disease (PD) in China until now.

Objective To investigate the types and causes of DRPs, and to assess the severity of these DRPs in PD patients in neurology wards.

Methods A retrospective study involving 209 PD inpatients was conducted at a tertiary hospital in China from January 2017 to December 2018. The identification and assessment of DRPs were based on the Pharmaceutical Care Network Europe (PCNE) tool version 8.03. The severity ratings of these DRPs was assessed based on the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) classification.

Results A total of 274 DRPs with an average of 1.31 ± 1.00 problems per patient were identified, in which 83.3% of the population had at least one DRP. Using the PCNE classification system, the most common domain of DRPs was "Other, P3" (62.8%), followed by "Treatment effectiveness, P1" (19.3%) and "Treatment safety, P2" (17.9%). A total of 88.7% of the DRPs were rated at severity categories B to D (causing no or potential harm), whereas 11.3% were rated as categories E to H (causing actual harm).

Conclusions These data indicate that the prevalence of DRPs is high among PD patients. The identification of different subtypes of DRPs may facilitate risk reduction for PD patients.

INTRODUCTION

Parkinson's disease (PD) is a progressive neurodegenerative disease that afflicts 1.7% of residents aged 65 years or older in China.¹ The incidence of PD is estimated to double to 8.7 million worldwide by 2030.² Impaired motor functions, such as bradykinesia, rigidity and muscle stiffness, tremor, gait disturbance and postural instability, are the disease's primary signs and symptoms. As the condition progresses, other non-motor symptoms may include disturbances in gastrointestinal function, sleep, blood pressure, or cognition, as well as psychological distress. The primary goals of therapy for patients with PD are to minimise their symptoms and to improve their quality of life with medications and surgery.

Because of the broad spectrum of symptoms, treatment frequently consists of complicated medication regimens. Moreover, the majority of PD patients are elderly and most of them experience comorbidities, including coronary heart disease,

hypertension, type 2 diabetes mellitus and hyperlipidaemia.³ These patients are at particular risk of experiencing drug-related problems (DRPs), including both complications arising from the drug itself, such as adverse drug reactions, and those attributable to the prescribing physician.

DRPs are defined as events or circumstances involving drug therapy that actually or potentially interfere with desired health outcomes.⁴ Optimisation of drug therapy to address and prevent DRPs can potentially shorten the length of hospital stays, save lives, and enhance patient quality of life. This study of DRPs is a complex process and a new challenge for clinical pharmacists.⁵ Recently published studies assessing clinical pharmacists' interventions showed they assisted in the early detection of DRPs and helped prevent consequent patient harms in hospitalised patients with neurological diseases.^{6,7} Further, Schröder *et al* examined the role community pharmacists play in identifying DRPs in PD outpatients, verifying 331 DRPs in 113 PD outpatients.⁸ Similarly, Hsu *et al*, studying outpatient care of heart disease patients, found that only 74.6% of patients received correct drug administration during the first 2 days post-admission.⁹ However, there is still a lack of studies on DRPs in hospitalised PD patients, both locally and globally, which limits the comparisons which can be drawn between current and prior research. Therefore, this study aims to investigate DRPs in PD patients in neurology wards of The First Affiliated Hospital of Jinan University. The findings from this study can help to determine the incidence rates and characteristics of DRPs among the PD population and can be used as preliminary data for future studies.

METHODS

Study design and setting

This was a retrospective study conducted at the neurology department at The First Affiliated Hospital of Jinan University in China, which is a tertiary public general teaching hospital with 1900 beds.

Study population and sampling sizes

The study included patients with idiopathic PD who were admitted as inpatients between 1 January 2017 and 31 December 2018. The two inclusion criteria were: a diagnosis of idiopathic PD by a neurology specialist fulfilling ICD-10 classification according to Diagnostic Criteria for Parkinson's Disease in China (2016 edition) and at least one anti-PD medication taken daily. Patients were excluded from the analyses if they exhibited atypical parkinsonian

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syndromes or secondary parkinsonism, had uncertain diagnoses, had hospitalisations with a duration <48 hours, or if relevant data were missing.

The sample size was determined using the Raosoft sample size calculator, which indicated a minimum of 197 patients were needed to achieve a 95% confidence level with a 5% margin of error and a conservative assumption of 50% response distribution.¹⁰

Data collection

The data were retrieved by the authors, who are pharmacists, from Electronic Medical Records and the Hospital Information System. Demographic and clinical characteristics such as age, gender, duration of hospital stay, duration of PD, past medical history, and concurrent medications were also collected.

Classification, identification, and assessment of DRPs

The Pharmaceutical Care Network Europe (PCNE) classification version 8.03, the most recent version during the study period, was used to categorise the DRPs.¹¹ All DRPs were identified by clinical pharmacists with neurology training, then confirmed by a specialist physician in neurology.

The PCNE creates guidelines and classifications to describe DRPs uniformly and serves as a process indicator in studies of pharmaceutical care outcomes.¹² The classification system, which is validated and updated regularly, has been used extensively by many recent studies.^{9 13 14} The advantage of this system is that DRP causes are classified into separate categories.¹⁵ The basic classification now has three primary domains for problems, nine primary domains for causes, and five primary domains for interventions.¹¹ Because clinical pharmacists did not provide a medication appraisal to prescribers nor directly contact patients during the review of DRP, the medication compliance of patients could not be comprehensively identified. Therefore, DRP cause codes such as “Dispensing”, “Drug use process” and “Patient related” were excluded.

The identified DRPs included adverse reactions, drug choice problems, dosing problems, drug use problems, and possible drug interactions. DRP identification was achieved through comparison of patients’ treatment with standard guidelines recommendations—such as Guidelines for the Treatment of Parkinson’s Disease in China (third edition) or Chinese Parkinson’s Disease Diagnostic Criteria (2016 edition)—or by referring to updated

references—such as UpToDate (version 21.2, Wolters Kluwer, Netherlands), Martindale: The Complete Drug Reference,¹⁶ or New Materia Medica.¹⁷ The authors, either clinical pharmacists (H Liu, Y Zhong, L Xue) or neurologists (Z Zheng, W Bi), were involved in determining the presence of DRPs. The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Index for categorising the DRP algorithm was used to determine the severity of the DRPs.^{18 19}

This classification consists of five categories based on ascending severity of the patient outcome: (1) circumstances or events that had the capacity to cause error (potential errors, category A); (2) medication errors (MEs) occurred without posing harm to patients (categories B and C); (3) MEs caused potential harm to patients (category D); (4) MEs caused harm to patients (of increasing severity, categories E, F, G, and H); (5) MEs resulted in a patient’s death (category I). The assessment of DRPs and severity ratings were performed by two pharmacists independently, and discrepancies were resolved through discussions.

Statistical analyses

All the data collected and extracted in this study were analysed using SPSS version 20 (IBM Corp). Individual-level and problem-level analyses were performed separately because many patients exhibited more than one DRP. Between-group differences were analysed using the χ^2 test, with Fisher’s exact adjustment where appropriate for categorical variables, and the t-test for continuous variables was used to compare means between groups. Mean age was analysed using the Mann-Whitney U test. Statistical significance was set at $p < 0.05$. All tests were two-tailed.

RESULTS

Demographic characteristics

A total of 209 PD patients fulfilled the inclusion criteria for this study, the demographics and clinical characteristics of which are listed in table 1. Males composed 51.0% (107/209) of the subjects. The minimum and maximum age of the patients were 43 and 88 years, respectively, with a mean of 69.1 ± 10.32 years; 75.1% (157/209) of participants had comorbidities, with 52.2% (109/209) of patients having hypertension, 17.2% (36/209) with diabetes, and 15.8% (33/209) with cerebrovascular disease. Taking five or more medications was common, being observed in 45.9% (96/209) of patients. Duration of PD years distribution

Table 1 Baseline demographics according to DRP

Demographics	Total (n=209)		With DRP		Without DRP	
	N	%	174	83.3%	35	16.7%
Gender, male	107	51.0	88	50.6	19	54.3
Gender, female	102	49.0	86	49.4	16	45.7
Age, mean $\pm$ SD, years	69.1	± 10.32	68.9	± 10.46	68.9	± 9.78
Length of hospital stay, days	6.1	± 5.64	11.0	± 4.8	10.2	± 4.0
Duration of PD (mean $\pm$ SD), years	10.8	± 4.61	8.0	± 7.47	5.5	$\pm 4.89^*$
Past medical history	157	75.1	132	75.9	25	71.4
Cerebrovascular disease	33	15.8	27	15.5	6	17.1
Coronary artery disease	30	14.4	22	12.6	8	22.9
Hypertension	109	52.2	97	55.7	12	34.3
Diabetes mellitus	36	17.2	31	17.8	5	14.3
Orthopaedic disorders	17	8.1	15	8.6	2	5.7
Chronic prostate disease	24	11.5	19	10.9	5	14.3
Others	81	38.8	66	37.9	15	42.9

* $p < 0.05$.

DRP, drug-related problem.

Table 2 Identified problems according to the PCNE DRP classification tool version 8.03 (n=274)

Primary domain	Type of problem	N	%
Treatment effectiveness, P1	No effect of drug treatment, P1.1	0	0
	Effect of drug treatment not optimal, P1.2	43	15.7
	Untreated symptoms or indication, P1.3	10	3.6
Treatment safety, P2	Adverse drug event (possibly) occurring, P2.1	49	17.9
Other, P3	Problem with cost-effectiveness of the treatment, P3.1	10	3.7
	Unnecessary drug-treatment, P3.2	162	59.1
	Unclear problem/complaint, further clarification necessary, P3.3	0	0

DRP, drug-related problem; PCNE, Pharmaceutical Care Network Europe.

varied by DRP status ($p/0.03$). A total of 83.3% (174/209) of patients had at least one DRP, with 274 total DRPs identified, with a mean of 1.31 ± 1.00 DRPs per patient.

DRPs identified for inpatients with PD

These data are shown in [table 2](#), grouped according to the PCNE DRP version 8.03 classifications. The most common DRP was “Other, P3” (62.8%; 172/274) followed by “Treatment effectiveness, P1” (19.3%; 53/274), and finally “Treatment safety, P2” (17.9%; 49/274). Within the “Other, P3” domain, “Unnecessary drug-treatment, P3.2” was the major sub-category (94.2%; 162/174) followed by the “Problem with cost-effectiveness of the treatment, P3.1” category (5.8%; 10/174).

Identified causes of DRPs

As shown in [table 3](#), “Drug selection, C1” was the major cause of DRPs (81.8%; 224/274) followed by “Dose selection, C3”

Figure 1 Medication categories that caused drug-related problems. DRP, drug-related problem; NSAIDs, non-steroidal anti-inflammatory drugs; PPIs, proton pump inhibitors.

(14.6%; 40/274) and “Treatment duration, C4” (3.6%; 10/274). Within the “Drug selection, C1” domain, the main cause was “No indication for drug, C1.3” (72.3%; 162/224) followed by “Inappropriate drug (within guidelines but otherwise contra-indicated), C1.2” (17.9%; 40/224).

Severity of the identified DRPs

As seen in [table 3](#), the potential severity ratings of the DRPs (n=274) were all in categories B to H. The low-severity categories B to D comprised 85.4% (234/274) of incidents, and high-severity categories E to H were the remaining 14.6% (40/274). Within the “Drug selection, C1” domain, 89.9% (218/224) of the DRPs were rated as severity categories B to D, and 15.0% (6/40) were rated as categories E to H.

Medication categories that cause DRPs

There were 274 recorded DRPs in the subjects. The medications behind these problems were grouped into the categories shown

Table 3 Identified causes according to the PCNE DRP classification tool version 8.03 and severity of DRPs based on the NCC MERP classification

Primary domain	Type of problem	N	%	Potential severity category B–D (n)	%	Potential severity category E–H (n)	%
Drug selection, C1	Inappropriate drug according to guidelines/formulary, C1.1	6	2.3	4	1.7	2	5.0
	Inappropriate drug (within guidelines but otherwise contraindicated), C1.2	40	15.1	38	16.2	2	5.0
	No indication for drug, C1.3	162	61.1	160	68.4	2	5.0
	Inappropriate combination of drugs or drugs and herbal medication, C1.4	6	2.3	6	2.6	0	0
	Inappropriate duplication of therapeutic group or active ingredient, C1.5	0	0	0	0	0	0
	No drug treatment in spite of existing indication, C1.6	10	3.8	10	4.3	0	0
Drug form, C2	Inappropriate drug form (for this patient), C2.1	0	0	0	0	0	0
Dose selection, C3	Drug dose too low, C3.1	0	0	0	0	0	0
	Drug dose too high, C3.2	0	0	0	0	0	0
	Dosage regimen not frequent enough, C3.3	3	1.1	3	1.3	0	0
	Dosage regimen too frequent, C3.4	3	1.1	3	1.3	0	0
	Dose timing instructions wrong, unclear or missing, C3.5	34	12.8	0	0	34	85.0
Treatment duration, C4	Duration of treatment too short, C4.1	0	0	0	0	0	0
	Duration of treatment too long, C4.2	10	3.8	10	4.3	0	0
Total		274	100	234	85.4	40	14.6

DRP, drug-related problem; NCC MERP, National Coordinating Council for Medication Error Reporting and Prevention; PCNE, Pharmaceutical Care Network Europe.

Table 4 Anti-Parkinson medication-related characteristics in patients according to DRP

Anti-PD medications administered	Number of patients using the medication	DRP, N (%)
Levodopa	209	30 (69.8)
Pramipexole	132	0
Piribedil	57	0
Entacapone	22	3 (7.0)
Selegiline	35	6 (13.9)
Trihexyphenidyl	14	4 (9.3)
Amantadine	2	0

DRP, drug-related problem; PD, Parkinson's disease.

in figure 1. The drug class that was most likely to cause DRPs was “Traditional Chinese medicine injection”. This was followed by “Neurotrophic agents” and “Anti-Parkinson agents”. Medications categorised as “Others” include compound amino acid injections, iron supplements, and vitamins. All of the patients were treated with a compound levodopa preparation for their PD, which was used alone or in combination with other drugs according to the patient's condition (table 4). The compound levodopa preparation showed the highest proportion of DRPs, followed by selegiline and entacapone.

DISCUSSION

This is the first study using the PCNE classification to assess the severity of identified DRPs in PD patients in inpatient wards at the department of neurology of a major Chinese hospital. In this study, the mean of 1.31 ± 1.00 DRPs per patient was less than what was found in a previous study of neurological patients, which was about two DRPs per patient.⁶ This could be explained by different patient conditions, as the prior study included patients who were in neurology wards and intensive care units. A study by Schröder identified 331 DRPs in 113 PD outpatients.¹⁹ These results differ significantly from our own as the methodology of our respective studies was not comparable. On the other hand, as presented here, there was still a high prevalence of DRPs, with 83.3% of the PD patient population having at least one DRP. This rate is higher than the previously reported rate (80%) at the internal medicine ward in Turkey.²⁰ Methodological issues of reporting and classification may lead to differences in the prevalence of DRPs between studies. However, the frequency of DRPs in this population of patients highlights the need for enhanced clinical pharmacy service.

The most frequent DRPs in this study were “unnecessary drug-treatment”, “effect of drug treatment not optimal”, and “adverse drug event (possibly) occurring”. Nevertheless, in a similar study conducted on geriatric patients in Malaysia,²¹ the most commonly reported DRPs were “drug choice problems” and “dosing problems”. The frequency of DRPs among different drug categories varies between studies, as this depends on different healthcare settings, methodologies (such as medical review or interview technique), study populations, and DRP classification (such as PCNE version 8.03 or PCNE version 6.02) used.

The major domains of DRPs in our study were classified as “Drug selection, C1” and “Treatment duration, C3” which together accounted for over 90% of the problems in this study. These findings were not in line with previous studies conducted by Ahmet *et al*¹² or Ma *et al*.¹³ Ahmet's study reported “Drug selection” and “Dispensing” as the most common DRPs. The types and causes of DRPs varied between countries by patient

number, study duration, the presence of a clinical pharmacist before the study, physician collaboration, and many other factors. Within the “Drug selection, C1” domain, “No indication for drug” was the major cause (72.3%) and followed by “inappropriate drug (within guidelines but otherwise contraindicated)” (17.9%).

Traditional Chinese medicine injections and neurotrophic agents were the top two drug classes that caused DRPs in this study. We found that inpatients with PD often received traditional Chinese medicine injections, such as *Salvia mil* and *Rhodiola rosea*, as a coronary heart disease treatment. Moreover, neurotrophic agents, such as oxiracetam and cerebroside carnosine, were also indicated to increase DRP risk. These drugs were usually used for the treatment of cerebrovascular disease rather than PD, and they were not recommended for PD patients in clinical guidelines. This might be common in China, as the administration of adjuvant medicines and Chinese patent medicines often find off-label use. This was also found in Can's study.²² Trimetazidine was used in PD patients with coronary heart disease although its instructions clearly indicated that it is forbidden for PD patients, as it can aggravate the symptoms of PD. The administration of trimetazidine in PD patients with coronary heart disease might be a result of imperceptible side effects and high acceptability of trimetazidine by both the doctors and patients. This makes it a unique source of DRPs for PD patients.

Flupentixol/melitracen (FM) is a compound preparation for the treatment of anxiety disorders, characterised by rapid symptom relief and the possibility of causing vertebral extracorporeal symptoms. PD symptoms were usually accompanied by anxiety and depression, and a 7 day coadministration of FM and a selective serotonin reuptake inhibitor (paroxetine or sertraline) were commonly used for rapid relief of these symptoms. However, this could also aggravate PD symptoms and is, therefore, also a unique DRP for PD patients.

Within the “Dose selection, C3” domain, “Dose timing instructions wrong, unclear or missing” was by far the major cause of DRPs (77.3%). The primary drug for PD patients was levodopa compound. These drugs can be affected by eating, especially protein, which leads to a decrease in absorption and a reduction in efficacy. Therefore, these drugs must be taken more than 1 hour before or 1.5 hours after a meal. However, 12.4% of prescriptions in this study did not clearly indicate the administration time of these drugs, which could result in poor efficacy.

In this study, 82.5% of DRPs were considered as “harmless” or “caused potential harm to patients” with NCC MERP classifications of B–D, while the remaining 17.5% of DRPs were deemed to have caused certain harm to the patients or led to longer hospital stays, with classifications E–H. Since the severity of harms caused by DRPs was analysed retrospectively via medical records, the completeness of these records might have had some impact on the result.

This study has several limitations and shortcomings. First, the retrospective nature of this study using medical records, established references, and a literature review may introduce bias or other uncertainties. The prevalence of DRPs might be underestimated, as some important data including physicians' and patients' perceptions could not be found in the medical records. Furthermore, it was difficult to obtain some relevant clinical data such as PD severity and patients' compliance with medication schedules. Missing data such as this may result in unwitting selection bias. Second, the Hospital Information System was only able to generate the list of PD patients who were registered from 1 January 2017 to 31 December 2018. Therefore,

the findings of this study may not generalise to the greater population of China, because of the relatively small sample size. Finally, this study used only part of the PCNE classification in assessing DRPs.

CONCLUSION

We observed a high frequency of DRPs in PD inpatients. Despite having significant DRP prevalence, PD patients were more likely to be non-adherent to their medications, particularly levodopa preparations. Interventions were required to reduce unnecessary medical expenses and risks. The findings indicate that enhanced prevention and management of DRPs in PD patients have a strong potential to improve the healthcare of these patients. It is our hope that the results of this study can be used to improve the efficacy of pharmacists in the treatment of PD patients. The findings can help clinical pharmacists with early detection and identification of the various types of DRPs, and awareness of the DRP-prone drugs discussed here can improve the prevention and management of DRPs in PD patients.

What this paper adds

What is already known on this subject

- Patients with Parkinson's disease (PD) patients should receive special attention and appropriate pharmaceutical care by healthcare professionals and especially by clinical pharmacists in order to prevent the development of drug-related problems (DRPs).
- The occurrence of DRPs has not been systematically investigated among hospitalised PD patients in China.
- The potential effect of the identification of DRPs on neurology departments in China by a clinical pharmacist has not been investigated.

What this study adds

- Substantial numbers of DRPs were identified among hospitalised PD patients in this study.
- Reviews for medication orders conducted by hospital pharmacists can identify DRPs.
- It is desirable that clinical pharmacy services are implemented in neurology departments in China.

Contributors HL and LFX designed the study. YXZ, ZHZ and WB collected and analysed the data. HL and SSQ organised the manuscript. HTZ reviewed the papers and revised the manuscript. All the authors (HL, LFX, YXZ, ZHZ, WB, HTZ and SSQ) have read and approved the final manuscript. All authors contributed toward data analysis, drafting and revising the paper and agree to be accountable for all aspects of the work.

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Competing interests None declared.

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Data availability statement Data are available in a public, open access repository.

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