

Prescribing patterns for Parkinson's disease in a South African patient population

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ABSTRACT

The primary aim of the study was to analyse the treatment of Parkinson's disease in a defined patient population in South Africa. A cross-sectional, retrospective drug utilization study was conducted on prescription data of a national community pharmacy group for 2010. A total of 25 523 products were prescribed to 5 168 patients. Most patients (59.17%) were females. The average age of patients was 69.57 ± 10.37 years. Levodopa-containing products constituted 46.50% of prescribing frequency. The highest sales value was attributed to a generic levodopa/carbidopa 100/25mg preparation, with the second being the innovator product of the same strength. Dopamine agonists (pramipexole and ropinirole) constituted 39.80% of prescribing frequency, followed by anticholinergic agents (9.20%), the MAO-B inhibitor selegiline (2.12%) and amantadine (1.80%). The cost of levodopa products in combination with a dopa decarboxylase inhibitor was 45.00% of the total expenditure on antiparkinsonian medication. Levodopa remained the gold standard for the treatment of Parkinson's disease. Further investigations need to focus on dosages, side effects, compliance and continuity of medication.

INTRODUCTION

Parkinson's disease is a progressive neurodegenerative disorder which affects one in every 100 people over the age of 65 years (Singh *et al.*, 2007). There is little reported on the incidence and prevalence of Parkinson's disease in Africa due to the lack of studies and the short life expectancy of the population (Okubadejo *et al.*, 2006). It has been shown, however, that the population aged 60 years and older is expected to double in sub-Saharan Africa (SSA) by 2030 and double again by the year 2050 (Velkoff and Kowal, 2006). The number of older people in SSA is growing faster than the rest of the world and will continue to do so in the future (Velkoff and Kowal, 2006). As ageing is a risk factor in the development of Parkinson's disease, it would be important to determine the incidence and prevalence of Parkinson's disease in SSA in order to determine the future economic burden society may face. Infectious diseases like HIV and malaria tended to

overshadow neurological disorders like Parkinson's disease in these regions (Pearse and Wilson, 2007). One study (Dotchin *et al.*, 2007) indicated that there is a low incidence of Parkinson's disease in SSA, but noted that studies had only been conducted on small populations previously.

Some reasons put forth for this low reported incidence include under-diagnosis of Parkinson's disease, differences in diagnostic criteria and early mortality in these populations due to other causes (Dotchin *et al.*, 2007). Two studies that aimed to determine the prescribing patterns of medication for Parkinson's disease will be discussed (Tan *et al.*, 2005; Leoni *et al.*, 2002). The studies showed that levodopa in combination with a decarboxylase inhibitor, such as carbidopa or benserazide, was the most commonly prescribed drug in both study populations. In the first study (Tan *et al.*, 2005) conducted in Singapore it was the levodopa/benserazide combination which was more often prescribed. Dopamine agonists made up 26.8% of the total medications used, with the next being benzhexol and then selegiline. The catechol-o-methyl transferase (COMT)-inhibitors and amantadine use was less than 10% (Tan *et al.*, 2005). The majority of the population was on monotherapy or two-drug combination therapy.

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Neurologists claimed that factors that most influenced their decisions included stage of the disease, cost of the drug, patient compliance and drug company sponsorship (Tan *et al.*, 2005). The second study (Leoni *et al.*, 2002) conducted in Italy also showed that levodopa was the most commonly prescribed drug (54.00%) followed by the dopamine agonists and the anticholinergic agents. These studies (Tan *et al.*, 2005; Leoni *et al.*, 2002) showed that 64.5% of the patients were also receiving medication unrelated to Parkinson's disease which had the potential to interact with their antiparkinsonian medication. Other medication being used by patients included benzodiazepines such as alprazolam, clonazepam, diazepam and lorazepam (Tan *et al.*, 2005; Leoni *et al.*, 2002). A South African study (Van der Merwe, 2010) demonstrated similar findings with dopaminergic agents averaging 69.00% of the total drugs prescribed per year over a four year period followed by the dopamine agonists. Apart from this study conducted on data from 2005 to 2008 (Van der Merwe, 2010), no other South African study on the prescribing patterns for Parkinson's disease could be found.

Due to the complicated nature of the symptoms and complications of Parkinson's disease and its therapy, medical treatment alone is not enough. This means that caring for the patient can become expensive (Keus *et al.*, 2012). It has been reported that as many as 18 different disciplines can become involved in the care of a patient suffering from Parkinson's disease (Keus *et al.*, 2012). Examples include physiotherapists, speech therapists, occupational therapists, dieticians, psychologists as well as others. Medical treatment, however, remains the mainstay of treatment. The primary aim of this study was therefore to analyse the treatment of Parkinson's disease in a defined South African patient population.

METHODOLOGY

The study was a retrospective drug utilization review. Drug utilization studies are conducted to determine the patterns of drug use, the quality of use, the determinants of use and the outcomes of drug use. Only patients aged 50 years and older were included in this study as Parkinson's disease is more common in patients of this age group (Movement Disorder Society Task Force on Rating Scales for Parkinson's Disease, 2003).

A national community pharmacy group provided a database containing all central nervous system (CNS) records for the year 2010. This study therefore focused on patients in the private health care sector with or without a medical aid. The data were anonymous and patients were identified only by a patient code, therefore patient confidentiality was maintained at all times. The data were analysed with Microsoft Access[®] and Excel[®].

From the total CNS database, 25 523 records for Parkinson's disease medicine were extracted for 2010. The data contained information about patients receiving antiparkinsonian medication on a chronic basis. Data fields included were patient profile number, product description, name of active ingredient and trade name, quantity sold, average sales value per product, gender,

age and calendar month. One Euro (€1.00) was equal to R9.38 (South African Rand), one US Dollar (\$1.00) was equal to R7.64 and one British Pound (£1.00) was equal to R11.48 at the time of the study (30 June 2010). Descriptive and basic inferential statistics were calculated. A limitation of the study was the absence of clinical information in the database and disease severity was not known. Ethical approval to conduct the study was obtained from the Research Ethics Committee (Human) of the Nelson Mandela Metropolitan University (NMMU).

RESULTS AND DISCUSSION

Demographic information of patients

A total of 5 168 patients were prescribed 25 523 antiparkinsonian products, with 3 058 (59.17%) of the patients being females and 2 110 (40.83%) being males. This gives a female to male ratio of 1:0.68. Many studies have shown that Parkinson's disease is more common in men than women (Fall *et al.*, 1996; Fargel *et al.*, 2007; Miller & Cronin-Golomb, 2010). However, two Japanese studies have shown a female prevalence in Parkinson's disease (Kimura *et al.*, 2002; Kusumi *et al.*, 1996). Another study conducted in France showed a prevalence ratio of Parkinson's disease of 1.40% in patients over the age of 65 years with no significant difference between males and females (Tison *et al.*, 1994). The total population aged 50 years and older in South Africa according to the midyear population estimate of 2010 was 14.94% with 8.30% being female and 6.64% being male (Statistics South Africa, 2011). This could partly explain why females were the dominant gender group in this patient population.

The average age of the patient population was 70.74±10.37 years. The reason for the decline in the number of patients beyond the age of 70 years could be due to mortality, or the general low life expectancy in South Africa, which was shown to be 53.3 years for males and 55.2 years for females in 2010 (Statistics South Africa, 2011). In addition, in South Africa, only 0.71% of the population is over the age of 80 years (Statistics South Africa, 2011).

Prescribing frequency of products

Table 1 indicates the average number of prescriptions dispensed to patients according to age and gender categories. The average number of products dispensed to male patients was 5.55±6.88 over the year 2010, whereas 4.51±5.44 was the average for females. The chi-squared test showed a statistical significant difference between male and female patients ($p < 0.05$) but this finding could be due to the large sample. The practical significance, as indicated by Cramér's V (0.07) was small. However, the majority of the products were dispensed to female patients (54.05%).

Average number of prescriptions dispensed by age and gender categories

Nine different active ingredients were prescribed for Parkinson's disease. The majority of antiparkinsonian products

dispensed (46.5%) were combination drugs containing levodopa with a decarboxylase inhibitor and some with a COMT-inhibitor as well. This was expected as levodopa is considered the gold standard treatment of Parkinson's disease (Singh *et al.*, 2007; Garret *et al.*, 1998; Stern, 2001). These results are in keeping with other studies conducted (Tan *et al.*, 2005; Leoni *et al.*, 2002; Van der Merwe, 2010).

Table. 1: Average number of prescriptions dispensed by age and gender categories.

Age categories (in years)	Average number of prescriptions (\pm SD)	
	Female	Male
50-59	3.44 \pm 2.70	4.10 \pm 4.34
60-69	4.46 \pm 2.56	5.92 \pm 6.94
70-79	4.99 \pm 3.92	5.78 \pm 3.63
80-89	5.24 \pm 7.41	5.81 \pm 8.82
\geq 90	4.27 \pm 5.82	5.58 \pm 5.70
All age categories	4.51 \pm 5.44	5.55 \pm 6.88

The second most dispensed group of drugs were the dopamine agonists which included pramipexole and ropinirole (39.80%). These were followed by the anticholinergic agents, benzhexol and orphenadrine, making up 9.20% of the total number of antiparkinsonian products dispensed. The MAO-B inhibitor selegiline and the anti-viral agent amantadine only made up 2.12% and 1.80% of the total number of products dispensed, respectively. When examining the frequency of antiparkinsonian product prescribing by gender, it was seen that males were mostly prescribed the levodopa-containing products (47.34%) whereas females were mostly prescribed the dopamine agonist pramipexole (38.47%). The products bromocriptine (a dopamine agonist), trihexyphenidyl (an anticholinergic agent) and rasagiline (a MAO-B inhibitor) are products recognized for the treatment of Parkinson's disease in South Africa according to the South African Medicines Formulary (SAMF, 2012) but were not prescribed to this patient sample in 2010. Bromocriptine is not the choice of dopamine agonist in the private sector as neurologists and patients have access to both pramipexole and ropinirole. Bromocriptine is instead used for cessation of lactation. A guideline for the treatment of Parkinson's disease published by the Scottish Intercollegiate Guidelines Network (2010) does not recommend the use of ergot derived dopamine agonists such as bromocriptine for the first line treatment of Parkinson's disease due to the risk of developing moderate to severe cardiac valvulopathy. According to the SAMF (2012) trihexyphenidyl is a drug more commonly used in the public health sector. The population analysed was primarily private sector patients and would therefore not utilize this product. Rasagiline was launched in 2009 in South Africa with a retail price of R1 024.38 which is considered to be expensive and which would deter many patients from opting to use it as medical aid schemes would not cover the full cost. This would result in increased out-of-pocket payments by patients. The total number of prescriptions for levodopa-containing products has shown an increase from March to April and then remained fairly constant for the rest of the year. The number of dopamine agonist prescriptions

did not vary greatly over the year; there was a slight increase from February to March and again from October to November, but with a constant range of 700 to 900 prescriptions per month throughout the year. The Drug Utilization 90% (DU90%) represents the drugs which account for 90% of the volume of prescribing (Bergman *et al.*, 1998). The levodopa-containing products, dopamine agonists, pramipexole and ropinirole, as well as the anticholinergic agent biperidine, constituted 90% of the overall drug prescribing for Parkinson's disease. According to the World Health Organization (WHO) the Defined Daily Dose (DDD) is the assumed average maintenance dose per day for a drug used for its primary indication in adults (Introduction to Drug Utilization Research, 2009). When calculating the average Prescribed Daily Dose (PDD) of levodopa-containing products ($n = 11\ 875$; 46.53%) it was found that the majority of prescriptions ($n = 2\ 056$; 17.31%) were for 300 mg daily which is half the DDD for levodopa. There were 1 659 (13.97%) prescriptions of 200 mg of levodopa daily and 1 207 (10.16%) prescriptions of 400 mg as a PDD. Only 994 (8.37%) prescriptions were equal to the 600 mg DDD. The average PDD of levodopa was 1 183.01 mg \pm 3 809.31 mg. This indicates the vast range of PDDs seen in the study population.

The dopamine agonists, pramipexole and ropinirole, were prescribed more frequently in the younger patient categories. The age group 60 to 69 years held the highest number of prescriptions ($n = 3\ 277$; 32.24%) and demonstrated an increase in the number of prescriptions throughout the year. When comparing this finding to the levodopa-containing products, it was seen that the 50 to 59 year age group received more dopamine agonists ($n = 2\ 169$; 57.98%) than levodopa-containing products ($n = 870$; 23.26%) throughout the year. When considering patients aged 70 years and older, levodopa-containing products ($n = 8\ 017$; 56.59%) were more commonly dispensed than dopamine agonists ($n = 4\ 718$; 33.30%). When calculating the PDDs of pramipexole ($n = 8\ 282$; 32.45%), the average was seen to be 1.21 mg \pm 1.82 mg. The most common PDD for pramipexole was 0.125 mg ($n = 2\ 861$; 34.54%), the second most common 0.25 mg ($n = 2\ 088$; 25.21%) and the third most common PDD was 0.5 mg ($n = 639$; 7.72%). Only 22 patients were prescribed 2.5 mg which is the DDD for pramipexole. When considering the average, most prescriptions ($n = 7\ 859$; 94.89%) were for PDDs lower than the DDD.

For ropinirole ($n = 1\ 882$; 7.37%), there were no patients receiving the WHO recommended DDD of 6 mg, however, the average PDD was seen to be 4.82 mg \pm 5.06 mg. The majority of prescriptions ($n = 239$; 12.70%) were for a PDD of 3.73 mg of ropinirole which is approximately 60% of the recommended WHO DDD. The second most common PDD was 7.47 mg ($n = 216$; 11.48%) and the third, 1.87 mg ($n = 138$; 7.33%). A total of 1 358 (35.81%) prescriptions were for PDDs lower than the DDD of 6 mg. Dopaminergic products included levodopa-containing products and dopamine agonists. It was shown that 63.76% of patients received a levodopa-containing product throughout the year while 61.26% of patients received a dopamine agonist. This indicated that patients were prescribed combination therapies.

Cost of medicine for Parkinson's disease

The total sales value of antiparkinsonian products for 2010 in this study was R8 500 496.49 with more spending attributed to male patients (55.46%). The average cost per prescription was calculated to be R333.05. The total sales value includes patient as well as medical aid payments. Figure 1 indicates the percentage of spending according to age and gender categories.

Percentage sales value of antiparkinsonian products according to age and gender categories

The majority of the cost (38.85%) was attributed to the age group 70 to 79 years. This group also constituted the largest proportion of patients (32.27%) and received the highest number of products (35.00%). Patients in this age group are most likely to be in the more severe stages of the disease and therefore may require higher doses and more supplementation in an attempt to effectively control symptoms of the disease and the side effects of the medications. The two individual products with the highest sales values were levodopa/carbidopa (45.67%) and pramipexole (25.63%), respectively. Levodopa/carbidopa 100 mg showed to be the product with the highest sales volume (number of prescriptions identified) (38.59%). The class of products with the highest percentage sales value were the dopamine replacement therapies containing levodopa, followed by the dopamine agonists pramipexole and ropinirole. The Drug Cost 90% (DC90%) indicates which products constituted 90% of the total cost of medication (Bergman *et al.*, 1998). The products which constituted the DC90% included the levodopa-containing products and the dopamine agonists pramipexole and ropinirole. This finding reflects that of the DU90%. The highest sales volume for a formulation of levodopa/carbidopa was the generic tablets with a strength of 25/100 mg (44.94%). The total sales for the levodopa/carbidopa generic product amounted to R2 448 829.10. The innovator, or original, product totalled at 41.68% less than the generic. Pramipexole with a strength of 0.125 mg had the highest sales volume. However, pramipexole with strength 0.25 mg had the highest total sales value.

This is due to the cost per pack. Pramipexole 0.125 mg costed R313.29 per pack of 100 tablets whereas pramipexole 0.25 mg costed R554.36 per pack of 100 tablets. There is no generic product available in South Africa for pramipexole. Of the immediate release formulations, ropinirole 1 mg tablets had the highest sales volume, but ropinirole 2 mg tablets had the highest total sales value.

This is due to the higher average cost price per pack of ropinirole 2 mg which was R603.20 per pack of 84 tablets, compared to that of ropinirole 1 mg which was R283.98 per pack of 84 tablets. Considering the extended-release formulations, ropinirole 8 mg tablets had the highest total sales value, but was only marginally higher in sales volume than ropinirole 4 mg tablets.

Table 2 indicates the average cost per pack of the various antiparkinsonian medications in this study as well as the single exit price (SEP). The single exit price stipulates the fixed maximum price at which manufacturers have to sell their medicine in South Africa, without any opportunity for offering discounts (Pretorius, 2011). Differences can be explained due to differences in pack sizes prescribed.

CONCLUSION

Very little has been published on the prescribing patterns of medicine for Parkinson's disease in South Africa. Yet, it is a condition that is on the increase given the aging population as well as better diagnostic techniques. Based on the prescribing trends identified in this study, it can be seen that levodopa was still the preferred first-line treatment for Parkinson's disease. The value of the dopamine agonists, COMT-inhibitors and MAO-B inhibitors in the management of Parkinson's disease may yet be realized through further research and gradual increases in prescribing. The total cost of levodopa products in combination with a dopa decarboxylase inhibitor amounted to 45% of the total expenditure on antiparkinsonian medication for the year 2010. Further investigations need to focus on dosages, side effects, compliance and continuity of medication.

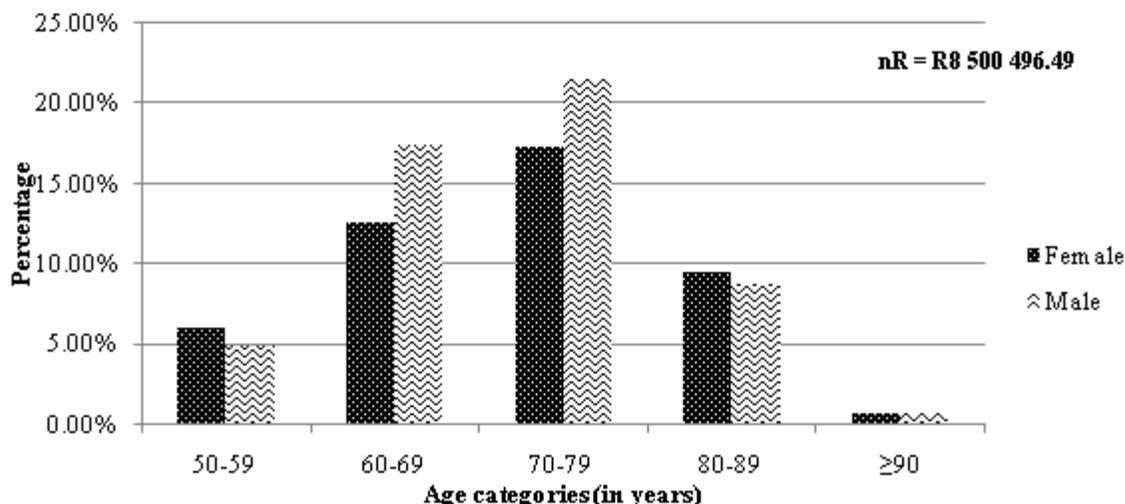


Fig. 1: Percentage sales value of antiparkinsonian products according to age and gender categories.

Table 2: Average cost per unit of dopaminergic products.

Active ingredients	Trade names	Average cost per pack	Single exit price (MIMS, 2010)
Levodopa/carbidopa	Carbilev [®] 25/100mg tablets (100)	R354.32	R356.14
	Carbilev [®] 25/250mg tablets (100)	R494.20	R505.81
	Sinemet [®] 25/100mg tablets (100)	R348.66	R364.36
	Sinemet [®] 25/250mg tablets (100)	R463.84	R498.33
	Sinemet [®] CR 50/200mg tablets (100)	R505.91	R523.78
	Teva [®] Carbi-Levo 25/100mg tablets (100)	R334.73	Unavailable
	Teva [®] Carbi-Levo 25/250mg tablets (100)	R445.44	Unavailable
Pramipexole	Pexola [®] 0.125mg tablets (100)	R313.29	R298.36
	Pexola [®] 0.25mg tablets (100)	R554.36	R591.99
	Pexola [®] 1mg tablets (100)	R1 028.06	R1 117.37
Ropinirole	Requip [®] 0.25mg tablets (84)	R115.38	R110.64
	Requip [®] 0.5mg tablets (84)	R204.23	R205.26
	Requip [®] 1mg tablets (84)	R255.62	R271.15
	Requip [®] 2mg tablets (84)	R471.98	R522.15
	Requip [®] 5mg tablets (84)	R759.09	R834.77
	Requip [®] XL 2mg starter pack tablets (42)	R298.13	R326.54
	Requip [®] XL 2mg tablets (28)	R208.50	R217.57
	Requip [®] XL 4mg tablets (28)	R263.34	R278.02
	Requip [®] XL 8mg tablets (28)	R444.07	R495.72

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