(12.0%), but the most frequent ADR was dyskinesia (11.5%). Serious ADRs and ADRs leading to discontinuation were infrequent and occurred in 10 (2.6%) and 11 (2.8%) pts, respectively.

The OFF time reduction was maintained over 1 year, and the mean change in OFF time from the DB baseline was -106.68 minutes at 28 weeks of the OL part, and it was -101.89 minutes at 52 weeks. Of note, when switched from placebo to 50 mg of OPC, the OFF time sharply decreased.

Conclusions: When a fixed 50 mg dose of OPC administered with a varying dose of L-dopa/DCI or anti-PD drugs to Japanese PD pts with end-of dose motor fluctuation, OPC was well tolerated for 1 year. Additionally, OPC had a lasting effect with a stable OFF time reduction.

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Safety of Gocovri in Clinical Practice: One-year Post-launch Pharmacovigilance Data

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Objective: To assess the real-world safety profile of Gocovri® (amantadine) extended release capsules one year post-launch.

Background: Gocovri received FDA approval in August 2017 for dyskinesia in Parkinson's disease (PD), with full commercial launch in January 2018. Gocovri is dispensed through specialty pharmacies whose representatives contact patients by phone on a monthly basis. All potential adverse events (AEs) reported during these calls are considered solicited and entered into a database.

Methods: First-year post-launch safety reporting for Gocovri was compared with the safety reporting in the phase 3 clinical trials.

Results: Post-launch adverse event (AE) rates were comparable to, and generally less than, AE rates in phase 3 studies, with Hallucination the most frequently reported (17% post-launch vs 21% phase 3). The post-launch hallucination rate for Gocovri is consistent with the 15% rate estimated for immediate release amantadine in an authoritative review (Parkes, 1981). Six MedDRA AE terms were reported at ≥3% post-launch that had lower rates in phase 3, 2 PD related (Balance disorder 6%; Tremor 5%), 3 relating to overall energy/strength (Fatigue 7%, Somnolence 5%, Asthenia 3%) and 1 nonspecific (Feel Abnormal 3%). Clinically relevant AEs, observed at <3% in phase 3, included, Delusions, Paranoia, Suicidality, and Apathy; post-launch rates were 1, 0.4, 0.2, and 0.1%, respectively. No post-launch AEs of neuroleptic malignant-like syndrome were reported. Fatalities in phase 3 were too few to provide a basis for comparison, but post-launch rates were consistent with literature-reported rates in PD. Most post-launch AEs showed an age-event relationship and were experienced by patients receiving 274 mg of Gocovri, irrespective of age. Preliminary investigations did not reveal any conspicuous associations between specific AEs and medical history or concomitant medications.

Conclusions: Post-launch AEs closely parallel the AE profile from phase 3. This may be due in part to frequent contact between specialty pharmacy and patient. The association between AE rates and age highlights the importance of dose adjustment for patients with age-related renal impairment and raises the possibility of other factors contributing to reduced tolerability with age. Dosing at <274 mg should be considered in patients who may be at heightened risk for AEs.

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Yerba mate tea (Ilex paraguariensis) exerts a neuroprotective effect on intrastriatal 6-OHDA-lesioned mice model of Parkinson's disease

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Objective: We set to investigate the possible neuroprotective effect of yerba mate (YM) consumption on dopaminergic neurons in a mice model of Parkinson's disease (PD).

Background: The motor symptoms of PD mainly emerge from the gradual degeneration and loss of dopamine neurons within the substantia nigra. Novel treatment approaches are needed as there is no current preventive therapy for PD. However, an inverse association was found between coffee intake or smoking and the occurrence of PD. Likewise, a case-control study revealed that consumption of 'mate' also has an inverse association with the risk of developing PD. Furthermore, we have recently shown that YM favors survival and growth of dopaminergic neurons in culture. Mate is an infusion from the plant Ilex paraguariensis (popularly known as yerba mate) widely consumed in several South American and Mediterranean countries. This infusion contains bioactive phenolic compounds with strong antioxidant and anti-inflammatory properties.

Methods: The extract of YM was obtained by 'cebada simulada', an extraction method that emulates the way it is commonly consumed and the main bioactive compounds (caffeine, theobromine, chlorogenic acid and rutin) were quantified by HPLC. A partial degeneration of dopaminergic neurons, as an early model of PD, was induced by a 6-OHDA injection into the striatum of wild type mice. Animals received water (control) or 'mate' as their only source of fluid. Different periods of YM administration and concentrations were evaluated. During the treatment, locomotor activity was evaluated in open field (OF) sessions, and after sacrifice, tyrosine hydroxylase (TH) immunohistochemistry was performed to evaluate the degree of dopaminergic denervation.

Results: The infusion of YM was well accepted by the animals. Mice that drank mate showed increased locomotor behavior compared to controls during the OF sessions. The denervation protocol we used induced a lesion degree ranging from 31 to 57%. Mice receiving a YM treatment for 4 months, after the injury with 6-OHDA, had a 12% higher density of dopaminergic fibers remaining in the striatum than control mice.

Conclusions: These results provide further evidence on the beneficial properties of YM and could lead to the development of novel preventive therapeutic interventions using YM in association with the most commonly used drugs to treat PD.

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Short term use of bromocriptine for treatment of Parkinson's disease during pregnancy

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Objective: Few reports describe experience with treatment of Parkinson's disease [PD] during pregnancy. About 5% of the population with PD are young onset (onset prior to 40 yrs); of these < 50% are female. [1] The incidence of pregnancy in this population seems to be very low, and sharing the experience of treating a patient with PD through a pregnancy is important.

Background: There are few reports as to the safety and efficacy of the use of dopaminergic therapies for PD in pregnancy. The limited number of cases prevents valid study as to potential outcomes. Many of the case reports focus on the outcomes of the patient's status, with escalation of PD during the pregnancy often noted. [2,3] Recognition of safe treatment options is needed for best control of patients through a pregnancy. Bromocriptine is an ergot-derived dopamine agonist [EDDA]. This class of medications has been recognized as leading to valvular heart disease [4]; bromocriptine, while considered safe for use during pregnancy, has been shown to impart the risk for a dose-related cardiac valve thickening. [5] Short-term use is less likely to cause structural valvular changes. Use of a related EDDA during pregnancy, cabergoline, has been reported as beneficial for symptom control without long-term complications. [6]

Methods: A 40 year old patient with PD presented to our clinic reporting that she was pregnant. Treatment included pramipexole, 0.25 mg TID, and carbidopa/levodopa 25/100, 1 TID, at that date. At 8 weeks gestation, she stopped all of her PD medications due to concern about potential fetal risk. Her PD symptoms (tremor, rigidity, bradykinesia) escalated; at 11 weeks she restarted carbidopa/levodopa on the advice of her obstetrician. At 16 weeks, she developed wearing off and bromocriptine was started in an effort to ease the motor fluctuations.

Results: The patient underwent cesarean section at 40 weeks and was delivered of a robust male infant with Apgar scores of 9 and 10 at 1 and 5 minutes. Following her delivery, she weaned the bromocriptine.

Conclusions: Pregnancy in patients with PD is an infrequent occurrence, due to the rare incidence of PD in women of child bearing age. Recognition that this can occur and knowledge of the treatment options is needed. While bromocriptine is not ideal for long-term use in patients with PD due to idiosyncratic risk for valvular heart disease, short-term use during pregnancy may provide significant symptomatic benefit.

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