

The Canadian Journal of Neurological Sciences

Le Journal Canadien des Sciences Neurologiques



HYPOTHESIS

- **Do the Corticospinal and Corticobulbar Tracts Mediate Functions in the Human Newborn?**
Harvey B. Sarnat 157

ORIGINAL ARTICLES

- **Traumatic Brain Injury, Aging and Reaction Time**
D.T. Stuss et al 161
- **Objective Investigation of Visual Function Using a Nondestructive Zoom-FFT Technique for Evoked Potential Analysis**
M.P. Regan and D. Regan 168
- **Optimal Indices for Testing Parkinsonian Rigidity**
Heikki Teräväinen et al 180
- **Abnormalities in Iron Metabolism in Multiple Sclerosis**
Leslie S. Valberg et al 184
- **Double-Blind Cross-Over Placebo Controlled Study of Flunarizine in Patients with Therapy Resistant Epilepsy**
E. Starreveld et al 187
- **Flunarizine as a Supplementary Medication in Refractory Childhood Epilepsy: A Double-Blind Crossover Study**
D. Keene et al 191

Complete Table of Contents page iii

ABSTRACTS

- **CANADIAN ASSOCIATION OF NEUROPATHOLOGISTS** 225
- **XXIVth CANADIAN CONGRESS OF NEUROLOGICAL SCIENCES**
..... 231

**XXIVth Canadian Congress of
Neurological Sciences
June 14-17, 1989
Ottawa, Ontario**

Program and Abstracts page 231

The Official Journal of

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The Canadian Neurosurgical Society
The Canadian Society of Clinical Neurophysiologists
The Canadian Association for Child Neurology

Volume 16, No. 2

May 1989



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Table of Contents

HYPOTHESIS

Do the Corticospinal and Corticobulbar Tracts Mediate Functions in the Human Newborn? <i>Harvey B. Sarnat</i>	157
--	-----

ORIGINAL ARTICLES

Traumatic Brain Injury, Aging and Reaction Time <i>D.T. Stuss, L.L. Stethem, T.W. Picton, E.E. Leech and G. Pelchat</i>	161
Objective Investigation of Visual Function Using a Nondestructive Zoom-FFT Technique for Evoked Potential Analysis <i>M.P. Regan and D. Regan</i>	168
Optimal Indices for Testing Parkinsonian Rigidity <i>Heikki Teräväinen, Joseph K.C. Tsui, Edwin Mak and Donald B. Calne</i>	180
Abnormalities in Iron Metabolism in Multiple Sclerosis <i>Leslie S. Valberg, Peter R. Flanagan, Ann Kertesz and George C. Ebers</i>	184
Double-Blind Cross-Over Placebo Controlled Study of Flunarizine in Patients with Therapy Resistant Epilepsy <i>E. Starreveld, F. de Beukelaar, A.F. Wilson, D.R. McLean and Helen P. Findlay</i>	187
Flunarizine as a Supplementary Medication in Refractory Childhood Epilepsy: A Double-Blind Crossover Study <i>D. Keene, S. Whiting, P. Humphreys and P. Jacob</i>	191
Neuropathy with Onion Bulb Formations and Pure Motor Manifestations <i>Roland N. Auer, Robert B. Bell and Mary Anne Lee</i>	194
Bilateral Hypoglossal Palsies: A Late Complication of Curative Radiotherapy <i>Eamon F. Johnston, Alex J. Hammond and J. Gregory Cairncross</i>	198
Progressive Multifocal Leukoencephalopathy with Gray Matter Involvement <i>S. Ledoux, I. Libman, F. Robert and N. Just</i>	200
Transient Anosognosia for Episodic Hemiparesis: A Singular Manifestation of TIA's and Epileptic Seizures <i>F. Grand'Maison, J. Reiher, M.L. Lebel and J. Rivest</i>	203
Intraparenchymal Epithelial (Enterogenous) Cyst of the Medulla Oblongata <i>Boleshaw Lach, Neville Russell, David Atack and Brien Benoit</i>	206
Cerebral Edema Associated with Meningioma <i>Shih-Tseng Lee and Swee Hsueh</i>	211
Computed Tomography, Magnetic Resonance Imaging and Pathological Correlations in a Case of Binswanger's Disease <i>M. Mascalchi, D. Inzitari, G. Dal Pozzo, N. Taverni and A.L. Abbamondi</i>	214
BOOK REVIEWS	219
NOTES AND ANNOUNCEMENTS	222
CALENDAR OF EVENTS	223
ERRATUM	223
CANADIAN ASSOCIATION OF NEUROPATHOLOGISTS – Abstracts	225
XXIVth CANADIAN CONGRESS OF NEUROLOGICAL SCIENCES – Program and Abstracts	231
INSTRUCTIONS TO AUTHORS	viii
ADVERTISERS INDEX	xxi



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The Canadian Journal of Neurological Sciences is published quarterly. The annual subscription rate is \$48 for Canada, \$48US for USA and elsewhere. Residents, Interns, Pre- and Post-Doctoral Studies \$24 per annum. Single copies \$15 each. All manuscripts and communications should be sent to: Canadian Journal of Neurological Sciences, P.O. Box 4220, Station C, Calgary, AB Canada T2T 5N1. Courier to: 117C-1330-15 Avenue, S.W., Calgary, AB Canada T3C 3N6. Telephone (403) 229-9575. COPYRIGHT© 1988 by THE CANADIAN JOURNAL OF NEUROLOGICAL SCIENCES INC. No part of this journal may be reproduced in any form without the prior permission of The Canadian Journal of Neurological Sciences. Mailed under second class registration number 3307. Postage paid at Calgary, Alberta. This journal is indexed by *Index Medicus*, *Excerpta Medica* and *Current Contents — Clinical Practice and Life Sciences*.

Le Journal Canadien des Sciences Neurologiques est publié trimestriellement. L'abonnement annuel est de 48 \$ au Canada et 48 \$US pour les Etats Unis et ailleurs. Internes, résidents, fellows pré et post doctoral: 24 \$ par année. Copie simple: 15 \$ Toutes les communications et les manuscrits doivent être adressés à Journal Canadien des Sciences Neurologiques, P.O. Box 4220, Station C, Calgary, AB Canada T2T 5N1. Par courrier: 117C-1330-15 Avenue S.W., Calgary, AB Canada T3C 3N6. (403) 229-9575

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Advertising representative/Représentant de publicité Reach Media Sales,
176 Wheeler Ave., Toronto, Ontario, Canada M4L 3V4 — 416-699-8207

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ACTIONS Parlodel (bromocriptine mesylate) is a dopaminomimetic ergot derivative with D₂ type dopamine receptor agonist activity, and has also D₁ dopamine receptor antagonist properties. The dopaminomimetic activity of bromocriptine in the striatum is considered responsible for the clinical benefits seen in selected patients with Parkinson's disease, when low doses of the drug are gradually added to levodopa therapy in patients on long-term treatment who develop late side effects of levodopa or no longer respond to the medication. Excessive dopaminomimetic drive may, however, provoke psychotic and other adverse reactions.

The extreme variability in G.I. tract absorption and the extensive and individually variable first-pass metabolism are responsible for the broad variability in plasma concentrations of bromocriptine and, in part, for the variability in dose response.

INDICATIONS* Parkinson's Disease: Parlodel (bromocriptine mesylate) has been found to be clinically useful as an adjunct to levodopa (usually with a decarboxylase inhibitor), in the symptomatic management of selected patients with Parkinson's disease who experience prominent dyskinesia or wearing off reactions on long-term levodopa therapy.

Patients on long-term treatment who are beginning to deteriorate on levodopa therapy may be controlled by reducing the dose of levodopa and adjusting the frequency and schedule of drug administration. Patients maintained on optimal dosages of levodopa who still experience prominent dyskinesia and/or end-of-dose failure may benefit from the concomitant use of Parlodel, by decreasing the occurrence and/or severity of these manifestations. Since rapid escalation of bromocriptine doses causes severe adverse reactions, it is recommended to combine a slow increase of Parlodel, usually with a concomitant, gradual and limited reduction of levodopa dosage. Continued efficacy of bromocriptine for more than two years has not been established and there is some evidence that its efficacy tends to wane. Evidence available indicates that there is no consistent benefit from bromocriptine in patients who have not responded previously to levodopa, and studies have shown significantly more adverse reactions in bromocriptine-treated patients than in patients treated with levodopa. Parlodel is not recommended in the treatment of newly diagnosed patients or as the sole medication in Parkinson's disease.

CONTRAINDICATIONS Other than sensitivity to ergot alkaloids, no absolute contraindications to treatment with Parlodel (bromocriptine mesylate) are known. For procedure during pregnancy see "Use in Pregnancy" under Precautions.

WARNINGS Long-term treatment (6-36 months) with Parlodel in doses of 20 to 100 mg/day has been associated with pulmonary infiltrates, pleural effusion and thickening of the pleura in a few patients. Where Parlodel was discontinued, these changes slowly reverted to normal.

PRECAUTIONS Parlodel (bromocriptine mesylate) may cause hypotension, primarily postural; periodic monitoring of the blood pressure, particularly during the first days of therapy, is advisable. In some patients dizziness (vertigo) may occur with Parlodel; patients should therefore be cautioned against activities requiring rapid and precise responses, such as driving an automobile or operating dangerous machinery, until their response has been determined.

Care should be exercised when administering Parlodel concomitantly with phenothiazines or antihypertensive agents. Due to drug interaction at the receptor site, dosage should be adjusted accordingly.

Alcohol should be avoided during treatment with Parlodel. In some patients, the concomitant use of Parlodel and alcohol has given rise to alcohol intolerance and an increase in the severity and incidence of Parlodel's possible adverse reactions.

Parlodel should always be taken with food. In cases

where severe adverse effects, such as nausea, vomiting, vertigo or headaches are severe or persisting, the therapeutic dosage of Parlodel should be reduced to half of one tablet daily (1.25 mg) and increased gradually to that recommended. The dopamine antagonist domperidone may be useful in the control of severe gastrointestinal side effects in parkinsonian patients receiving Parlodel (see Drug Interactions).

As with all medication, Parlodel should be kept safely out of the reach of children.

Use in Pregnancy: If the patient wishes to become pregnant, Parlodel (bromocriptine mesylate) should be stopped as soon as possible after conception is suspected. In this event immunological confirmation should be done immediately. When pregnancy is confirmed, Parlodel, like all other drugs, should be discontinued unless, in the opinion of the treating physician, the possible benefit to the patient outweighs the potential risk to the fetus.

In human studies with Parlodel (reviewed by Turkali, I.), there were 1410 reported pregnancies, which yielded 1236 live and 5 stillborn infants from women who took Parlodel (bromocriptine mesylate) during early pregnancy. Among the 1241 infants, 43 cases (31 minor and 12 major) of congenital anomalies were reported. The incidence (3.46%) and type of congenital malformations and the incidence of spontaneous abortions (11.13%) in this group of pregnancies does not exceed that generally reported for such occurrences in the population at large.

Use in Parkinson's Disease: Use of Parlodel (bromocriptine mesylate), particularly in high doses, may be associated with mental confusion and mental disturbances. Since patients with Parkinson's disease may manifest varying degrees of dementia, caution should be exercised when treating such patients with Parlodel.

Parlodel administered alone or concomitantly with levodopa may cause visual or auditory hallucinations. These usually resolve with dosage reduction, but discontinuation of Parlodel may be required in some cases. Rarely, after high doses, hallucinations have persisted for several weeks following discontinuation of Parlodel. Caution should be exercised when administering Parlodel to patients with a history of myocardial infarction, particularly if they have a residual atrial, nodal or ventricular arrhythmia.

Symptomatic hypotension can occur and, therefore, caution should be exercised when administering Parlodel, particularly in patients receiving antihypertensive medication. Periodic evaluation of hepatic, hematopoietic, cardiovascular and renal function is recommended.

Drug Interactions: The concomitant use of erythromycin may increase bromocriptine plasma levels.

Domperidone, a dopamine antagonist, may cause increases in serum prolactin. In so doing, domperidone may antagonise the therapeutically relevant prolactin lowering effect of Parlodel. It is possible that the antitumorigenic effect of Parlodel in patients with prolactinomas may be partially blocked by domperidone administration.

ADVERSE REACTIONS The most frequently observed adverse reactions are nausea, vomiting, headache and gastrointestinal side effects such as abdominal pain, diarrhea and constipation. All these effects may be minimized or even prevented by giving small initial doses of bromocriptine and by taking it with food.

Postural hypotension which can, on rare occasions, lead to fainting and "shock-like" syndromes has been reported in sensitive patients. This is most likely to occur during the first few days of Parlodel treatment.

When bromocriptine is added to levodopa therapy, the incidence of adverse reactions may increase. The most common newly appearing adverse reactions in combination therapy were: nausea, abnormal involuntary movements,

hallucinations, confusion, "on-off" phenomenon, dizziness, drowsiness, faintness, fainting, vomiting, asthenia, abdominal discomfort, visual disturbance, ataxia, insomnia, depression, hypotension, shortness of breath, constipation and vertigo.

Less common adverse reactions include anorexia, anxiety, blepharospasm, dry mouth, dysphagia, edema of the feet and ankles, erythromelalgia, epileptiform seizures, fatigue, headache, lethargia, mottling of skin, nasal stuffiness, nervousness, nightmares, paresthesia, skin rash, urinary frequency, urinary incontinence, urinary retention and rarely signs or symptoms of ergotism such as tingling of fingers, cold feet, numbness, muscle cramps of feet and legs or exacerbation of Raynaud's syndrome.

Abnormalities in laboratory tests may include elevation of blood urea nitrogen, SGOT, SGPT, GGPT, CPK, alkaline phosphatase and uric acid, which are usually transient and not of clinical significance.

The occurrence of adverse reactions may be lessened by temporarily reducing dosage to one-half tablet two or three times daily.

SYMPTOMS AND TREATMENT OF OVERDOSE There have been several reports of acute overdosage with Parlodel (bromocriptine mesylate) in children and adults. No life threatening reactions have occurred. Symptoms reported included nausea, vomiting, dizziness, drowsiness, hypotension, sweating and hallucinations. Management is largely symptomatic; the cardiovascular system should be monitored. Metoclopramide can be used to antagonize the emesis and hallucinations in patients who have taken high doses.

DOSAGE AND ADMINISTRATION Parlodel (bromocriptine mesylate) should always be taken with food.

Although Parlodel (bromocriptine mesylate) has been found clinically useful in decreasing the severity and frequency of "on-off" fluctuations of late levodopa therapy, the decision to use bromocriptine as adjunctive treatment and the selection of dosage must be individualized in each case. A low dose is recommended. The initial dose of Parlodel is one half of a 2.5 mg tablet (1.25 mg) at bedtime with food to establish initial tolerance. Thereafter, the recommended dosage is 2.5 mg daily in two divided doses, with meals, (half a 2.5 mg tablet twice daily). The dosage may be increased very gradually, if necessary, by adding an additional 2.5 mg per day, once every 2 to 4 weeks, to be taken always in divided doses with meals. Increments should usually not exceed 2.5 mg. Clinical assessments are recommended at two week intervals or less during dosage titration, to ensure that the lowest effective dosage is not exceeded. The usual dosage range is from a few milligrams to 40 mg daily in two or three divided doses with meals. The median dose varies with the experience of individual investigators, but can be around 10 mg daily or higher. During initial titration it is recommended that the dosage of levodopa should be maintained, if possible. Subsequently, it might be desirable to combine a slow increase of bromocriptine with a concomitant, limited and gradual reduction of levodopa.

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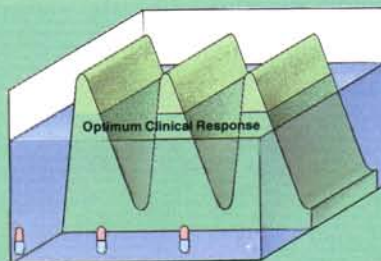
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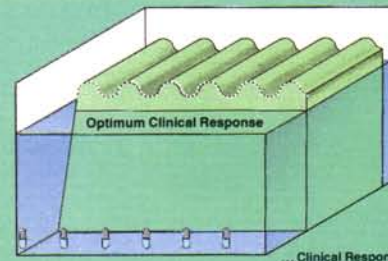
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