Summary

Phase 2 Clinical Study of ^{123}I-IBF, a Dopamine D_2 Receptor Imaging Agent, to Evaluate Clinical Efficacy and Safety in Parkinson's Disease and Parkinson Syndromes

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A Phase 2 multicenter trial of ^{123}I-IBF, (*S*)-5-iodo-7-*N*-[(1-ethyl-2-pyrrolidinyl)methyl]carboxamido-2,3-dihydrobenzofuran, was conducted to evaluate its clinical efficacy and safety in 158 patients with Parkinson's disease (PD) or Parkinson syndromes (PS). SPECT data were acquired at two hours (2H-SPECT), after intravenous injection of ^{123}I-IBF (167 MBq). Additional SPECT scan at three hours (3H-SPECT) and dynamic SPECT scan at most until one hour were performed when possible. No severe side effects due to ^{123}I-IBF injection were observed. The sensitivity, specificity and accuracy for discriminating PS from PD using the striatal specific binding count-to-frontal cortex count ratio (St/Fc−1) in 3H-SPECT were 72.7%, 81.0% and 78.1% in 64 clinically definite cases (i.e., typical cases), respectively. The putamen-to-caudate ratios were significantly lower in striatonigral degeneration compared with those in PD. The contralateral-to-ipsilateral ratios against the symptomatic side of tremor and/or rigidity in the patients with PD (Hoehn & Yahr I) were significantly higher than the left-to-right ratios in the normal controls. St/Fc−1 in 3H-SPECT was significantly lower in the patients showing a poor response to levodopa than in those showing a good response. The dopamine D_2 receptor binding potential (k_3/k_4), obtained by dynamic SPECT based on compartment model analysis, correlated well with the striatal specific binding count-to-occipital cortex count ratio. These results suggest that ^{123}I-IBF is a promising agent for differential diagnosis and pathophysiological evaluation of PD and PS.

Key words: ^{123}I-IBF, Dopamine D_2 receptor, Phase 2 study, Parkinson's disease, Parkinson syndrome, Single photon emission computed tomography.