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Clinical Expert Summary
Midodrine hydrochloride (Bramox®) 2.5 mg and 5 mg tablets

Midodrine hydrochloride (Bramox®) in adults for the treatment of severe orthostatic hypotension due to autonomic dysfunction when corrective factors have been ruled out and other forms of treatment are inadequate.

1. Existing guidelines

One group of experts have developed a local protocol for the safe administration and titration of midodrine. The European Society of Cardiology guidelines for the diagnosis and management of syncope (2009) were also identified.

2. Disease prevalence/incidence

Experts report that the prevalence of orthostatic hypotension due to autonomic failure is difficult to estimate. It is rarely seen as an isolated entity, being more commonly seen in association with other conditions (e.g. Parkinson's disease, multiple sclerosis or diabetes). A unit specialising in Parkinson's disease reports approximately 6–10 patients receiving midodrine. One cardiac expert stated at present there are 120-150 patients with blood pressure regulatory problems under regular follow-up in their area, and estimated 71 of these patients are currently receiving midodrine. One other expert advised that they prescribe midodrine to approximately six patients per year who have blood pressure instability and recurrent hypertensive collapses, however due in most cases to causes other than autonomic dysfunction.

3. Current treatment options

Options include education (e.g. advice about postural change and standing for long periods of time), increased fluid and salt intake and support stockings (although one expert did not believe the latter were effective).

Pharmacological treatments include fludrocortisone, domperidone, midodrine and more rarely used options: pyridostigmine, octreotide and erythropoietin. Droxidopa may be available for use in the future. One expert stated that potential side effects with fludrocortisone are fluid retention and swelling. Midodrine and droxidopa are both reported to cause unwanted supine hypertension, which is a problem already in those with Parkinson's disease.

Midodrine raises standing blood pressure; however one expert stated that although standing blood pressure may improve in patients, there is no evidence that symptoms or the quality of life is improved.

4. Unmet needs

Clarification of the meaning of autonomic failure and the symptoms requiring treatment is needed. There is a need for a specialist assessment centre for people with autonomic dysfunction. Orthostatic hypotension is a huge problem in patients with Parkinson's disease and current options are not effective.

5. Knowledge of product in given indication

Experts felt that midodrine treatment should be offered following education on self-management strategies, increased fluid and electrolyte intake and fludrocortisone. A preference for specialist supervision in prescribing was expressed. One expert felt that together with education and aggressive adherence to increased fluid and electrolyte intake, midodrine has a very beneficial role to play in refractory cases.