

EFFECT OF B3-ADRENERGIC RECEPTOR AGONIST ADMINISTRATION ON BLOOD PRESSURE IN THE ELDERLY

Hypothesis / aims of study

Mirabegron, β_3 -adrenergic receptor agonist used for treatment of overactive bladder, reportedly has fewer adverse effects such as dry mouth and constipation, compared to anticholinergic drugs, and can be used with relative safety in the elderly.

However, a Drug Safety Update in Japan states that "Elevation of blood pressure has been observed. Therefore, blood pressure should be measured before starting administration of this drug, as well as periodically measured during administration." Thus, we prospectively studied the effect of mirabegron on blood pressure in the elderly.

Study design, materials and methods

The subjects were overactive bladder patients aged 65 or older on mirabegron. Patients with either a systolic blood pressure (SBP) of 180 mmHg or higher or a diastolic blood pressure (DBP) of 110 mmHg or higher at the start of administration were excluded. Blood pressure was measured at the start of mirabegron administration and 12 weeks later.

Results

A total of 211 patients (male n = 117) were assessed; mean age was 77.8 ± 6.8 . BP was measured before and after administration: SBP from 128.4 ± 16.4 to 127.2 ± 17.6 mmHg ($P = 0.355$) and DBP from 71.5 ± 10.6 to 69.5 ± 10.2 mmHg ($P = 0.012$). Patients were divided into young-old (n = 70, age 65 - 74) and old-old (n = 141, age 75 or older) groups. No significant change was seen in SBP before and after administration in young-old or old-old patients: from 123.3 ± 14.6 to 124.8 ± 13.0 mmHg ($P = 0.372$) and from 131.0 ± 16.8 to 128.4 ± 19.4 mmHg ($P = 0.149$), respectively. No significant elevation was seen in DBP before and after administration in young-old or old-old patients: from 70.2 ± 9.9 to 69.3 ± 10.0 mmHg ($P = 0.463$) and from 72.1 ± 11.0 to 69.7 ± 10.3 mmHg ($P = 0.001$), respectively.

There were 46 cases (22.0%) with clinically significant SBP elevation of 10 mmHg or more: 17 (24.3%) were young-old and 29 (20.6%) were old-old patients. In younger patients (n = 54) aged 64 or less administered mirabegron during this clinical trial, significant SBP elevation was seen in 12 cases (22.2%), which did not differ from changes observed in the elderly.

Patients' characteristics and the changes of blood pressure

	Entire N = 211			Young-old N = 70			Old-old N = 141		
	0W	12W	P value	0W	12W	P value	0W	12W	P value
Gender M / F	117 / 94			30 / 40			87 / 54		
Age	77.8 ± 6.8			70.2 ± 2.8			81.1 ± 8.0		
*SBP	128.4 ± 16.4	127.2 ± 17.6	0.355	123.3 ± 14.6	124.8 ± 13.0	0.372	131.0 ± 16.8	128.4 ± 19.4	0.149
**DBP	71.5 ± 10.6	69.5 ± 10.2	0.012	70.2 ± 9.9	69.3 ± 10.0	0.463	72.1 ± 11.0	69.7 ± 10.3	0.001

*systolic blood pressure **diastolic blood pressure

Interpretation of results

No overall elevation of blood pressure was seen before and after mirabegron administration; however, SBP elevation of 10 mmHg, which is thought to be a risk factor for systemic disorders associated with cardiovascular disease, was seen in about 20%, and was comparable to that seen in younger persons.

Concluding message

Because the elderly are generally more prone than younger people to high blood pressure, and because chronic blood pressure elevation may induce various complications, adequate monitoring for changes in blood pressure is necessary during mirabegron administration.

Disclosures

Funding: None **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Nagasaki University Hospital **Helsinki:** Yes **Informed Consent:** Yes