Overactive bladder (OAB) patients with more severe urgency had higher satisfaction with mirabegron dose escalation from 25 mg to 50 mg

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Hypothesis/aim of study

- Mirabegron is the first β3-adrenoceptor agonist used in clinical practice.
- In Taiwan, the recommended starting dose is 25 mg once daily, with an option to increase it to 50 mg, which is similar to the guidelines in the USA and Canada, but different from that of Japan.
- Less study investigate the additive efficacy of mirabegron dose escalation from 25 mg to 50 mg in Asian patients.
- We investigated **the additive efficacy of mirabegron 50 mg** and tried to find **patients with higher satisfaction with dose escalation.**

METHODS

- Patients aged ≥ 20 years with OAB symptoms receiving **mirabegron 25 mg** once daily were enrolled. The dose of mirabegron **was escalated to 50 mg** in all patients.
- Results were assessed using OAB symptom score (OAB-SS), patient perception of intensity of urgency scale (PPIUS), international prostate symptom score (IPSS) total, voiding (IPSS-V) and storage subscore (IPSS-S), patient perception of bladder condition (PPBC), and quality-of-life index (QoL-I) before and 3 months after dose escalation.
- The maximum flow rate (Qmax), voided volume and post-void residual (PVR) volume were also measured.
- Patients rated their symptoms as compared to that before dose escalation by using a validated global response assessment (GRA) scale, which comprises of 7 points, from markedly worse (-3) to markedly improved (+3).
- **Satisfactory treatment results** was considered if patients reported **GRA≧1**.
- Baseline parameters and parameters changed were **compared between those with GRA≧2 and GRA<2.**

Table 1 Parameters changed before and after dose escalation to 25 mg

N=92	Baseline	3M	P-value
OAB-SS	6.18±3.96	5.35±3.49	**0.021**
PPIUS	1.97±1.69	1.98±1.70	0.948
IPSS-V	4.09±4.75	3.90±4.57	0.693
IPSS-S	5.21±3.59	4.60±3.31	0.065
IPSS-T	9.29±6.82	8.50±6.26	0.205
PPBC	1.86±1.58	1.35±1.52	**0.002**
QoL-I	2.43±1.72	1.82±1.52	**0.000**
GRA	0.00±0.00	1.48±1.33	**0.000**
Qmax	13.9±5.95	11.7±5.54	0.103
VoL	198±127	151±102	0.129
PVR	38.0±44.8	40.1±47.7	0.806

CONCLUSIONS

- Mirabegron dose escalation from 25 mg to 50 mg in Asian patients is **safe** and **feasible.**
- Dose escalation was suggested for those with **severe urgency or UUI** even 25 mg was used.
- Patients with more improvement of urgency and storage symptoms had higher satisfaction.

RESULTS

- A total of 124 patients (29 female and 95 male; mean age, 67 years) with OAB were enrolled.
- **75%** of patients had **GRA≧1** after dose escalation to 50 mg. The OAB-SS, PPBC and QoL-I also improved significantly (Table 1).
- Six patients developed adverse events (AEs) include hypertension, constipation, dysuria, dry mouth and leg edema.
- All AEs were mild and tolerable, but one patient had urinary retention after dose escalation.
- Patients with **PPIUS≧3 before dose escalation** had significantly more improvement of urgency and storage symptoms than those with PPIUS<3.
- The decreased of PPBC and QoL-I was also more significant in patients with PPIUS≧3.
- Patients with GRA≧2 had significantly more reduction of urgency and storage symptoms (Table 2).

Table 2 Comparisons between patients with GRA≧2 and GRA<2

		3M GRA≥2 (N=55)	3M GRA≤1 (N=37)	P-value
OABSS	B	**6.27±3.97**	6.05±4.00	
	3M	**4.87±3.36**	6.05±3.61	0.053
	Δ	**-1.40±3.34**	+0.00±3.38	
PPIUS	B	2.11±1.69	1.76±1.71	
	3M	1.84±1.68	2.19±1.75	**0.037**
	Δ	-0.27±1.67	+0.43±1.41	
IPSS-V	B	3.93±4.51	4.32±513	
	3M	2.95±4.00	5.32±5.03	0.051
	Δ	-0.98±3.77	+1.00±5.20	
IPSS-S	B	**5.16±3.63**	5.27±3.59	
	3M	**3.85±3.00**	5.70±3.47	**0.008**
	Δ	**-1.31±3.24**	+0.43±2.66	
IPSS-T	B	**9.09±6.61**	9.59±7.21	
	3M	**6.80±5.52**	11.0±6.51	**0.003**
	Δ	**-2.29±5.18**	+1.43±6.41	
PPBC	B	**1.82±1.53**	1.92±1.67	
	3M	**1.00±1.26**	1.86±1.72	**0.016**
	Δ	**-0.82±1.40**	-0.05±1.56	
QoL-I	B	**2.15±1.65**	2.86±1.75	
	3M	**1.13±0.88**	2.84±1.69	**0.002**
	Δ	**-1.02±1.51**	-0.03±1.46	
GRA	B	**0.00±0.00**	0.00±0.00	
	3M	**2.38±0.49**	0.14±1.00	**0.000**
	Δ	**+2.38±0.49**	+0.14±1.00	
Qmax	B	12.8±1.83	**14.5±7.47**	
	3M	14.0±4.93	**10.2±5.57**	**0.031**
	Δ	+1.25±4.80	**-4.31±5.60**	
VoL	B	175±55.6	212±156	
	3M	170±102	140±105	0.269
	Δ	-4.25±105	-72.5±148	
PVR	B	24.4±36.5	45.8±48.4	
	3M	43.0±60.9	38.4±40.7	0.131
	Δ	+18.6±28.2	-7.43±41.4	