

## LOW DOSE OF TADALAFIL CAN FURTHER IMPROVE SYMPTOMS OF LUTS/BPH PATIENTS ALREADY TREATED WITH TAMSULOSIN.

### Hypothesis / aims of study

Although  $\alpha$ 1 adrenoceptor blockers ( $\alpha$ -blocker) are the first line treatment in LUTS/BPH patients, they cannot relieve symptoms in all cases. Recently phosphodiesterase type 5 inhibitors (PDE5I) sildenafil, vardenafil and tadalafil [1] were reported to be effective in LUTS/BPH patients with or without erectile dysfunction (ED). We conducted an open-label clinical study to investigate the effect of tadalafil in patients with LUTS/BPH who had already been treated with tamsulosin.

### Study design, materials and methods

Men at least 50 years old with LUTS/BPH, who had been under treatment by tamsulosin for 12 weeks with little effect, were eligible for this study. Inclusion criteria were a total International Prostate Symptom Score (IPSS) of 15 or greater, QoL score of 3 or greater, a maximum urinary flow rate (Qmax) of 4 to 15 mL/s, a prostate volume estimated by ultrasonography of 20mL or greater, a postvoid residual urine volume (PVR) of < 100 mL. Men were not required to have a history of ED and the frequency of sexual intercourse was not discussed at the entry.

Patients were asked to take 5mg of tadalafil with tamsulosin everyday for 12 weeks. The primary endpoint was the change in IPSS and IIFE-5 from baseline. Safety was assessed by adverse events, physical examination, vital signs and laboratory tests. Change of Qmax and PVR were measured. The number of circulating angiogenic cells (CAC) was measured [2] before and after tadalafil treatment.

### Results

Fifteen patients completed study. The change in the total IPSS from baseline was -6.6 (p<0.05). The change in the storage symptom was greater than that in voiding symptom (-3.7 v.s. -2.9, p<0.05). The change in IIEF-5 from baseline was +5.2 (p<0.05). The change in QoL from baseline was -1.8 (P<0.05). These beneficial effects lasted for 12 months after treatment period. Qmax and PVR did not change significantly. The number of CAC increased significantly. No drug-related adverse events were reported.

### Interpretation of results

Low dose of tadalafil with tamsulosin significantly improved symptoms in LUTS/BPH patients who did not respond to tamsulosin alone. Increase in number of CAC may play a role to maintain the effect of treatment.

### Concluding message

Low dose of tadalafil combined with  $\alpha$ -blocker can be a treatment option in those patients who showed unsatisfactory results with  $\alpha$ -blocker monotherapy.

### References

1. J Urol. 180: 1228-1234, 2008
2. Atherosclerosis 196: 313-319, 2008

<b>Specify source of funding or grant</b>	<b>None</b>
<b>Is this a clinical trial?</b>	<b>No</b>
<b>What were the subjects in the study?</b>	<b>HUMAN</b>
<b>Was this study approved by an ethics committee?</b>	<b>Yes</b>
<b>Specify Name of Ethics Committee</b>	<b>Ethical committee of Dokkyo Medical University Koshigaya Hospital</b>
<b>Was the Declaration of Helsinki followed?</b>	<b>Yes</b>
<b>Was informed consent obtained from the patients?</b>	<b>Yes</b>