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

Hypothesis / aims of study
Although α1 adrenoceptor blockers (α-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 20 mL 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 IIEF-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 QoL 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 responded 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 α-blocker can be a treatment option in those patients who showed unsatisfactory results with α-blocker monotherapy.

References