**Urinary Stem Cell Factor as a Novel Diagnostic and Therapeutic Biomarker for Overactive Bladder**

**Introduction and Objective**: Recent reports have demonstrated that c-kit acts as not only a marker of interstitial cells of Cajal, but also plays a significant role in the control of bladder spontaneous activity, and could be a target for the clinical treatment of overactive bladder (OAB). We previously demonstrated that c-kit ligand, stem cell factor (SCF), was expressed in the urothelium of human bladder and secreted by the urothelium. The objective of this study was to investigate whether SCF could be a potential biomarker for diagnosis and therapeutic efficacy of OAB.
**Materials and Methods:** One hundred ninety-eight normal healthy volunteers (male:female=98:98) without OAB, lower urinary tract symptoms or other urinary tract-related diseases, were enrolled as a control to determine the reference range of urinary SCF level. In addition, 280 patients with untreated OAB were also enrolled. OAB was diagnosed on the basis of the overactive bladder symptom score (OABSS). Urinalysis was performed to rule out urinary tract infection and microscopic hematuria. Urinary SCF levels were measured by enzyme-linked immunosorbent assay (ELISA). All experiments were carried out in triplicate. The total urinary SCF levels were normalized to the concentration of urinary Cre. The study was approved by the ethics committee of our institution.
**Results**: The reference range of SCF/Cre was obtained by measuring the values in healthy volunteers. The 95% reference range was calculated as (mean-1.96 SD) to (mean+1.96 SD), and provided that the data were normally distributed. According to this calculation, the normal range of urinary SCF was determined under 3.6x10-4. There was no significant difference in urinary SCF/Cr level between male and female. The average urinary SCF level was significantly higher in OAB patients (12.7±11.9 x10-4) than in the healthy volunteers group (1.7±0.9 x10-4; $p<0.00001$). The urinary SCF level showed a significant positive correlation with OABSS ($r=0.67$, $p=0.001$). It was significantly decreased after 12-week administration of anticholinergic agents ($p<0.05$), and showed a significant positive correlation with improvement of OABSS ($p<0.004$).
**Conclusions**: The urinary SCF could be a novel diagnostic and therapeutic biomarker for overactive bladder, because it showed significant correlation with severity of OAB and efficacy of anti-cholinergic agents.