

## TADALAFIL VS. PLACEBO ON URETERAL STENTING RELATED SYMPTOMS, A RANDOMIZED CONTROLLED TRIAL- RESULTS OF THE PILOT STUDY

### Hypothesis / aims of study

Ureteral stenting related symptoms including pain, frequency and urgency is very common in endo-urological procedures, which cause significant effects on patient health-related quality of life (1). Tadalafil is one of the recent therapeutic options for improvement of lower urinary tract symptoms related to benign prostatic hyperplasia (2). Tadalafil is well tolerated by the patients and its side effects are dose related while other current treatments like  $\alpha$  blockers or antimuscarinics may not the same(3). This study is evaluated the effects of Tadalafil on of lower urinary tract symptoms, pain, general health, sexual life and work status of patients with ureteral stents based on Ureteral Stents Symptom Questionnaire. Since the lack of the similar studies a pilot study was conducted to calculate the appropriate sample size.

### Study design, materials and methods

Eighteen patients age 18- 70 years with unilateral ureteral stent will enroll to the pilot study of this randomized controlled trial from 1st December2013 to January 2014. The study was a single center, triple blind, parallel-design and the participants was randomized into A or B (as intervention or control) groups by computerize random blocking which conducted at Imam Reza teaching hospital and the Urology Department of Tabriz University of Medical Sciences in Iran. All patients were treated by placebo or Tadalafil (Chemidarou company) 10 mg daily for 28 days. Data collected immediately after the 28 days treatment period by using Ureteral Stents Symptom Questionnaire. Informed consent was obtained from all participants.

### Results

Basic characteristics of the all eighteen participants were similar at the beginning of the study. After four weeks the mean urinary symptoms score in group I and group II was 28 and 30.9 respectively (PV = 0.14). Body pain score was 19.3 in group I and 24.1 in group II (PV = 0.11). General health score was 13.6 and 13.4 respectively in group I and II (PV = 0.54). Work performance score in group I was 21 and in group II was 20 (PV = 0.62). Sexual matters score in group I and II was 2.7 and 5.4 respectively (PV = 0.018). Additional problems score was 11.3 in group I and 11.6 in group II (PV = 0.41).

### Interpretation of results

Ureteral Stents Symptom Questionnaire shows the symptom scores of the six different categories, including: LUTs, pain, sexual condition, general health, work performance and additional problems. Although the scores of the intervention group in the first three categories was less than control but only the sexual condition was significantly better in group I. Calculated sample size based on superiority hypothesis with clinical importance margin of 0.59 (25% Standard Effect Size), was 54 patients for each group.

### Concluding message

The results of the pilot study may estimates a significant different in lower urinary tracts symptoms, pain and sexual scores in intervention vs. placebo groups.

### References

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### Disclosures

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