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Safety and Efficacy of Low-intensity Extracorporeal Shockwave in 5 the Treatment of Erectile Dysfunction: a multi-center, double-blind, randomized sham-controlled clinical trial

Zhong-Cheng XIN (Peking University, China)

### 1 Current Status of Men's Health in Korea

#### Sae Woong Kim

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Along with a constant increase in the average life span in Korea, the desire for quality of life among the elderly population has also increased rapidly compared with that in the past. Many symptoms and conditions are caused by low serum-testosterone such as decreases in mobility, sexual function, and energy. The prevalence of Late-onset hypogonadism (LOH) in general population is quite variable in Asian studies. According to the statistics of the Health insurance review and assessment service of Korea (HIRA), the number of male infertile patients in Korea increased 1.5 times in four years. Traditionally, the prevalence of LOH is higher in men over 40 years of age, but the prevalence of young males is increasing in recent years due to hormonal imbalance caused by environmental factors such as smartphone electromagnetic waves and instant food. However, due to social awareness that men's health problems such as LOH and ED are equated with the inability of men, many patients often hide symptoms and avoid visits to hospitals, seek out untried therapies that are online, or leave their symptoms. Appropriate diagnosis, treatment and prevention efforts are needed for men's health.

# 2 Androgen receptor CAG repeat length as a risk factor of late onset hypogonadism in a Korean male population

#### Du Geon Moon

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Introduction and Objectives: Androgen receptor (AR) CAG polymorphism that modulates the effect of testosterone has been found to influence sexual function. However, correlation between AR CAG repeat length and clinical factors of late onset hypogonadism is unclear and there are only few studies from Asian population. In this study we explored the relationship between AR CAG repeat length polymorphism and late onset hypogonadism (LOH) in a Korean male population.

Materials and Methods: The association between AR CAG repeat length was analyzed in a total 263 Korean men from 2014 to 2015. LOH was diagnosed by serum testosterone level of <3.5ng/mL and androgen deficiency in the aging male questionnaire positive. AR CAG repeat length was determined by microsatellite fragment sizing. Clinical factors and questionnaire related with LOH (patient health questionnaire-9 (PHQ), aging male symptom scale (AMS), and international index of erectile function (IIEF-5)) were analyzed with AR CAG repeat length.

Results: Mean age of the patients was  $61.2 \pm 10.9$  years and mean AR CAG repeat length was  $26.2 \pm 5.1$ . Mean serum testosterone levels was  $2.6 \pm 0.7$  in men with LOH and  $6.0 \pm 2.0$  in men without LOH, respectively. A Total of 33 men (12.5%) were diagnosed with LOH. Men with LOH showed significant longer AR CAG repeat length compared with men without LOH (30.1 vs 25.6, p<0.001). As CAG repeat length increased, AMS total and AMS psychotic/somatic/sexual subscore increased(r=0.219 r=0.168, r=0.160, r=0.241) (p=0.001, p=0.006 p=0.001, p=0.001) and IIEF-5 score decreased, significantly (r=-0.187 p=0.002). In multivariate analysis showed that CAG and total AMS score were independently associated with LOH. (OR=1.3, 0.9, P<0.001, 0.005, respectively)

Conclusion: In conclusion, AR CAG repeat length was associated with prevalence of LOH and clinical symptoms of LOH in a Korean male population. Longer CAG repeat length was identified as one of the risk factor of LOH in Korean male.

### 3 Y chromosome microdeletions in Japanese infertile male.

#### Masashi Iijima

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Y chromosome microdeletion is one of the few obvious causes of spermatogenic failure. In the guidelines of the European Association of Urology (EAU) and European Academy of Andrology / European Molecular Genetics Quality Net Work (EAA / EMQN), genetic tests are recommended for severe oligozoospermia, and nonobstructive azoosperma. EAA / EMQN guidelines for Y chromosome microdeletions shows 6 sequence tag site (STS) markers are recommended to detect microdeletions basically, but in our experience, it was considered that only these recommended markers were insufficient for assessing in Japanese. So we developed a new detection kit suitable for Japanese. In the new kit, we finally adopted the 21 markers. Detection was carried out with a suspension array using Luminex X MAP technology. With this kit, domestic testing, accurate diagnosis with a small amount of sample, and more finely detailed classification become possible.

This kit has become clinically usable from July 2014, and tests are currently being conducted at many facilities. I would like to show the recent Japanese data after the start of testing in the presentation.

# 4 Dynamic analysis of ejaculation using color Doppler ultrasonography in patients with ejaculatory dysfunction.

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Herein, we describe the dynamic analysis of ejaculation using color Doppler ultrasonography (CDUS) in healthy volunteers and in patients with ejaculatory dysfunction. We consider that the dynamic analysis of ejaculation using CDUS could contribute to the diagnosis and the images can also provide useful information for patients. First, we explain how to perform USCD and how to analyze the images. Second, we present CDUS images of normal ejaculation and various ejaculatory dysfunctions. Finally, we report updates on two cases of ejaculatory dysfunction in which USCD was useful for the acquisition of new information on the status of ejaculation. One is loss of seminal emission. Dynamic analysis showed contraction failure of the seminal vesicles just before ejaculation and less rhythmical ejection of the seminal fluid from the seminal vesicles. The other is orgasmic disorder due to benign prostatic hyperplasia. Strong compression of the ejaculatory duct was observed and ejection of seminal fluid was very slow into the ejaculatory duct. Furthermore, seminal fluid streams went slowly from the seminal vesicles toward the prostate urethra via the ejaculatory duct.

## 5 Safety and Efficacy of Low-intensity Extracorporeal Shockwave in the Treatment of Erectile Dysfunction: a multi-center, double-blind, randomized sham-controlled clinical trial

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INTRODUCTION AND OBJECTIVES: To evaluate the safety and efficacy of Low-intensity Extracorporeal Shockwave (LI-ESWT) in the Treatment of Mild-Moderate Erectile Dysfunction.

METHODS: A multi-center, double-blind, randomized sham-controlled clinical trial was conducted. 70 patients (46 cases for LI-ESWT treatment group and 24 cases for the placebo group) at age 20-70 years, who had mild or moderate ED evaluated with the International Index of Erectile Function erectile function domain (IIEF-EF) were recruited for this study. Screening, treatment and results were performed in sequence. 4 weekly sessions for the treatment stage: A total of 5000 shockwaves were applied for each treatment and 4 areas were conducted including: 900 shockwaves in right and left crura, and 1600 shockwaves in each site. Effectiveness was assessed according to the International Index of Erectile Function domain (IIEF-EF), questions 2 and 3 of the Sexual Encounter Profile (SEP), Global Assessment Question (GAQ) scores, and Erection Hardness Scale (EHS) at baseline and at 1 and 3 months after treatment. The study was approved by Peking University First Hospital ethics committee, and all patients signed an informed consent form.

RESULTS: For Full Analysis Set (FAS) and Per-Protocol Set (PPS), the average IIEF-EF increased significantly from  $18.04\hat{A} \pm 3.94$  (17.90 $\hat{A} \pm 3.77$ ) at baseline to  $22.02\hat{A} \pm 4.13$  ( $21.95\hat{A} \pm 4.06$ ) at 1 month post treatment, and was  $22.54\hat{A} \pm 3.98$  ( $22.49\hat{A} \pm 3.90$ ) at the 3 months follow-up. The clinical efficasy of LI-ESWT on mild-moderate ED showed 67.39% (73.17%) after 1months post treatment VS 20.83% (23.81%) in the placebo group and is 69.57% (73.17%) after 3 months post treatment VS 20.83% (23.81%) in the placebo group by FAS (PPS). SEP, GAQ, EHS analysis were also significantly improved compared to the placebo controls (p<0.05). No side effects were reported in this study.

CONCLUSIONS: These results indicated that LI-ESWT showed safe and effective treatment patients with mild or moderate ED, without adverse events. Further study is recommended.