

CONCLUSIONS: Due to the fact that the results have not been unblinded yet, it is difficult to reach an objective conclusion. However, based on the quantitative data, we can assume that UTI-like symptoms in patients with negative culture tests may be associated with elective urological procedures, such as mesh surgeries.

Source of Funding: None

GG01-31

A RANDOMIZED CONTROLLED TRIAL OF BOVHYALURONIDASE AZOXIMER IMPACT ON BIOFILMS IN EJACULATE OF PATIENTS WITH CHRONIC PROSTATITIS AND INFERTILITY

Andrey O. Morozov*, Stanislav V. Vovdenko, Elizaveta E. Bragina, Margarita N. Boldyreva, Ofelia A. Whitaryan, Dmitry A. Zubkov, Sergey N. Allenov, Mikhail S. Evdokimov, Magomed A. Gazimiev, Leonid Spivak, Moscow, Russian Federation

INTRODUCTION AND OBJECTIVE: Bacterial biofilms play a significant role in the development of antibiotic resistance, recurrence of infection and even the rate of the pathogen detection in the prostate secretion. Consequently, there is a need to identify new drugs that can effectively target biofilms. The objective of our study is to assess the impact of bovyhialuronidase azoximer on laboratory parameters and the state of bacterial biofilms in ejaculate when added to standard antibacterial therapy in patients with chronic prostatitis and impaired fertility.

METHODS: Patients with chronic bacterial prostatitis and complaints of infertility were enrolled in the randomized controlled trial. The study was approved by the Sechenov University IRB. The patients completed NIH-CPSI, IPSS, QoL questionnaires, underwent RT-PCR and cultural study of prostate secretion, ejaculate or third urine portion, light-optical and electron microscopy of the ejaculate. Then they were randomized to "antibacterial drug (4 – 6 weeks) + bovyhialuronidase azoximer (3.000 IU, 12 weeks)" or "antibacterial drug only" treatment groups. Questionnaire, laboratory tests dynamics and compliance were assessed at the 3-months follow-up visit. Adverse events and the fact of the disease recurrence were recorded at 3- 6- and 12-months follow-up visits.

RESULTS: 98 patients were enrolled. The results of the NIH-CPSI scale indicated a reduction in total score across domains 1, 3 and 4 in the experimental group compared to controls (-1.6 vs -1, $p<0.001$; -1 vs -0.4, $p<0.001$; -1.5 vs -1, $p<0.001$ respectively). The electron microscopy indicated a greater reduction in the number of neutrophils (-3.2 vs -0.6, $p<0.001$) and bacterial colonies (-2.2 vs -0.4, $p=0.003$) in the experimental group. In the bovyhialuronidase azoximer group, the intercellular matrix was observed to disappear, and single bacteria were found to lie separately in some cases, with damage to the bacterial cell wall also noted. In contrast, the morphology of microcolonies in the control group remained unaltered. The number of disease recurrences was found to be lower in the experimental group, both after six (5 (10.6%) vs 20 (40.8%), $p<0.001$) and 12 months (18 (38.3%) vs 44 (89.8%), $p<0.001$). Additionally, there were no cases of multiple relapses within a 12-month period in the experimental group (0 (0%) vs 24 (49%), $p<0.001$).

CONCLUSIONS: The combination of bovyhialuronidase azoximer with antibiotic therapy has been demonstrated to produce statistically significant improvements in NIH-CPSI scores, a reduction in the number of leukocytes and bacteria present in ejaculate, prostate secretion, and urine following prostate massage, a reduction in the recurrence rate of chronic prostatitis, and a reduction in the number of bacterial biofilms compared to antibiotic monotherapy.

Source of Funding: NPO Petrovax Pharm LLC

GG01-32

A RANDOMIZED PLACEBO-CONTROLLED COMPARISON OF PROLONGED-RELEASE SILDENAFIL WITH A STANDARD SILDENAFIL

Andrey O. Morozov*, Svetlana R. Bogatova, Leonid Spivak, Moscow, Russian Federation

INTRODUCTION AND OBJECTIVE: Sildenafil citrate (Viagra) intake is associated with frequent side effects like headache or hemodynamic instability. Vildeggra is a prolonged release drug form and such optimization of pharmacokinetics might reduce the frequency and manifestation of side effects. This study aimed at evaluating the efficacy of 4-week therapy with Vildeggra, it's safety and the manifestation of side effects in patients with ED in comparison to placebo and Viagra.

METHODS: Vildeggra is a generic drug of Sildenafil, enclosed in Hypromellose shell. That ensures an active substance gradual release and a long-lasting effect of Vildeggra in comparison to Viagra. The duration of Vildeggra effect is up to 13 hours, Viagra – up to 4 hours. Triple cross-randomized open-label placebo controlled clinical trial was conducted to study outcomes of treatment with the drug "Vildeggra" 50 mg in comparison with the drug "Viagra" 50 mg. This clinical trial was conducted after IRB approval in accordance to the Protocol, World Medical Association Declaration of Helsinki and Tripartite guideline on Good Clinical Practice (ICH GCP). Patients: men aged 19 to 60 years with an established diagnosis of ED. The following methods were applied in the study: physical examination, ultrasound of penile blood flow during erection with Viagra, ECG, IIEF, IIEF-5, SEP, GAQ questionnaires, patient diary, laboratory methods. Patients in the experimental group were administered monotherapy in the following sequence: 28 days with Vildeggra, a week-long wash-out period, 28 days of placebo, another one week wash-out period, and 28 days of Viagra. In the control group, the drug intake sequence was different: Viagra-placebo-Vildeggra.

RESULTS: 60 patients were enrolled in this study. Vildeggra increased sexual activity according to questionnaires and patient diaries 1.6 times higher than Viagra and 2.4 times higher than placebo. The frequency of adverse events during Vildeggra therapy was 1.6 times lower comparing to Viagra. During the wash-out period after taking Sildenafil, the EF continued to improve, that indicates the aftereffect of Vildeggra and Viagra. As a result of 28-day therapy with Vildeggra the EF assessment on the IIEF-5 scale increased significantly by 49.3%, $p<0.05$ in comparison with placebo. For Vildeggra vs Viagra baseline values were 14 ± 3.8 and 13.9 ± 3.5 , respectively, and after 1 month 20.9 ± 3 and 20 ± 3.4 , $p=0.678$. According to the questionnaires in 96.6% of patients the erection lasted long enough to have successful sexual intercourse with ejaculation. At the end of the study the ECG were without any clinically significant negative dynamics, Vildeggra did not have any negative effect impact on laboratory analyses.

CONCLUSIONS: Vildeggra is not inferior to Viagra in terms of efficacy while it is better tolerated by patients. That influenced the higher frequency of Vildeggra intake compared to Viagra.

Source of Funding: LLC "Ozon"

GG01-33

THE ROLE OF AMBIENT AI SCRIBES IN CLINICAL DOCUMENTATION: A PILOT STUDY IN A UROLOGY OUTPATIENT CLINIC IN A TERTIARY CENTER

Julene Ong, Joshua Tung, Gerald Sng, Daniel Lim, Xinyan Yang*, Jonathan Tan, Iffat Bin Mohamad Rafi, Henry Ho, Singapore, Singapore

INTRODUCTION AND OBJECTIVE: The growing burden of clinical documentation in electronic health records has led to increased physician burnout and dissatisfaction. Time spent on documentation during patient visits detracts from meaningful communication, weakening the patient–physician relationship. Ambient artificial intelligence (AI) scribes, which leverage machine learning to capture and process conversations in real-time, present a promising solution by