

**Conclusion:** Even if many patients with good pharmacological control of the seizures report only minimal impairment of the sexual activity, others show important alterations in vital areas like sexual relations.

## T09-P-03

### Is endothelial apoptotic cell increment the major player in diabetic ED? An anatomoclinical study

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**Objective:** Our previous studies with animal models suggested that loss of erectile tissue cell integrity may be a relevant mechanism involved in erectile dysfunction (ED). To evaluate this hypothesis, we characterized vascular and smooth muscle cell (SMC) structure and viability in human cavernosal fragments of normal potent and diabetic impotent individuals. We further compared these results to patient age, arterial risk factors, Penile Nitric Oxide release test (PNORT) response to intracavernous injections (ICI) of vaso-active medications.

**Design and Methods:** 13 erectile tissue samples were harvested from diabetic impotent patients and 5 normal non-diabetic potent controls. Evaluation of vascular and SMCs was performed by immunohistochemistry for von Willebrand Factor and  $\alpha$ -smooth muscle actin. Tissue integrity was assessed by TUNEL assay and an index of apoptotic cell density (ACD) defined (number of apoptotic cells/tissue area (mm<sup>2</sup>)). These results were compared to patient clinical data as aforementioned.

**Results:** Results showed that normal controls had a low ACD (7,15/mm<sup>2</sup>), compared to diabetics, which presented a higher ACD (23,82/mm<sup>2</sup>). Apoptotic cells in diabetics were located mainly in the cavernous endothelium and perivascular areas. Higher ACD correlated with low PNORT and ICI responses and with severe penile arterial disease. Increased age and number of arterial risk factors may play a role in decreasing endothelial function.

**Conclusions:** Apoptotic cells are increased in diabetic vascular and perivascular cavernosal tissue, demonstrating that apoptosis is one of the main mechanisms involved in endothelial dysfunction in diabetic-ED. PNORT appears to be a promising non invasive test to evaluate penile endothelial functioning.

## T09-P-04

### Efficacy of ED treatment with PDE5-inhibitors in the Italian real clinical practice contest: longitudinal data from the EDOS study

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EDOS is an observational perspective study enrolling patients affected by Erectile Dysfunction wishing to receive a treatment. The study has been performed in the real clinical practice contest, and clinicians were free to prescribe any therapy for ED and to change therapy in each moment. A significative percentage of patients continue to assume the starting treatment. These subgroups allow a comparison analysis about efficacy of the different treatments employed.

1419 men, that spontaneously asked to their GP or to a specialist to start a treatment for ED or to change their ongoing therapy, were enrolled; 714 completed the 6months therapy assuming the baseline prescribed drug, in a continuous way: Tadalafil (n=535), Sildenafil (n=75), Vardenafil (n=66), other drugs or non pharmacological treatment(n=38). Efficacy was assessed by the IIEF-Questions 6,7,14; time concerns' domains, spontaneous behavior and self-confidence of SF-PAIRS; EDITS-Question1; SI-Questions 1,2; GAQ1,2.

Patients reported the longer gap between drug's assumption and the moment in which they could start their intercourse. To compare the treatment groups, a multivariate analysis adjusted to the basal differences has been used.

In terms of patient's efficacy, satisfaction, self confidence and spontaneous behavior, there are no statistically significant differences.

The time concerns domain of the SF-PAIRS is highly improved in Tadalafil: the gap elapsed between assuming drug and the intercourse was 21.4hours with Tadalafil, 6.6hours with Sildenafil and 7.7hours with Vardenafil.

The present observational study confirms that the PDE5-Is having no real differences in terms of efficacy. Tadalafil is, however, characterized for its lasting efficacy that determines a better impact concerning the anxiety of planning an intercourse and completing it before the drug's time of action is over.

## T09-P-05

### Design of Phase III pivotal trials of flibanserin in female Hypoactive Sexual Desire Disorder (HSDD)

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**Objective:** To present the design of three Phase III North American trials, which will assess the efficacy and safety profile of flibanserin, a novel centrally acting agent, in premenopausal women with Hypoactive Sexual Desire Disorder (HSDD).

**Methods:** The Dahlia (511.70), Violet (511.71), and Daisy (511.75) studies are prospective, multicenter, randomized, double-blind, placebo-controlled, parallel-group trials, designed to assess the effects of flibanserin in premenopausal women with a primary diagnosis of generalized, acquired HSDD. Every study consists of a 4-week baseline period (no medication), 24-week double-blind treatment period, and 4-week follow-up period after discontinuation of study medication. Designs are identical except for the flibanserin doses tested: 25 mg bid/50 mg bid/50 mg qhs/placebo in Dahlia; 50 mg qhs/100 mg qhs/placebo in Violet; 25 mg bid/50 mg qhs uptitrated to 50 mg bid/50 mg qhs uptitrated to 100 mg qhs/placebo in Daisy. Co-primary endpoints are monthly sum of responses to a daily question on sexual desire measured by an electronic diary (e-Diary For HSDD Trials©; e-Diary), comparing 4-week baseline with weeks 21-24, and change in frequency of satisfying sexual events, measured by the e-Diary. Secondary endpoints include change in distress related to sexual desire. Prospective safety assessments include evaluation of menses and sex hormones adverse events.

**Results:** These trials are ongoing. Results will be presented in 2009.

**Conclusions:** These North American Phase III trials will determine the efficacy and safety of 24 weeks' flibanserin treatment in premenopausal women with HSDD, and determine minimal effective and most tolerable dosages for this indication.

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## T09-P-06

### Sexual dysfunction in patients with temporal lobe epilepsy

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**Objective:** the current study was carried out in order to find any possible relationships between seizure semiology, their frequency, antiepileptic drugs treatment and affective disorders and sexual disorders in epileptic patients.

**Design and methods:** Two groups of epileptic patients with (100 persons) and without (50) sexual disorders were compared in study. Munich Personality Test (MPT; SCL-90; Hamilton Depression Scale and National Hospital Scale for Severity of Seizures (NHS3) were used in study.

**Results:** Obtained results have shown that libido reduction and disharmonic sexual relationships were the most fre-

quent complaints in epileptic patients and has occurred in 75% of patients. Patients with sexual dysfunctions were mostly characterized by temporal lobe epilepsy, concomitant depressive disorder, frequent complex partial seizures and long duration of epilepsy compared with epileptic patients without sexual disorders.

**Conclusion:** Sexual dysfunctions in patients with epilepsy seem to have interrelationship with temporal epilepsy with co-morbid depression and represents one facet of Geschwind-Gastout triad. Suggestion can be made that mesial temporal epilepsy is risk factor for possible sexual dysfunctions development. The therapy methods should be elaborated for improvement of quality of life in patients with temporal lobe epilepsy and sexual dysfunctions.

## T09-P-07

### Clinical and psychopathological features of frustration of a sexual desire

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**Objective:** The present research is undertaken with the purpose of studying interrelation of frustration of a sexual desire and a mental pathology with definition of their clinical features at patients of both floors and an establishment of the factors promoting occurrence and development of infringements libido, development of complex therapeutic actions.

**Design and method:** The basic methods of research clinical-psychopathological and clinical-sexological. Also in research have been used statistical methods.

**Results and conclusions:** At complex studying at 32 patients (21 man and 11 women), addressed in branch of sexual pathology of the Moscow scientific research institute of psychiatry, in the age of from 22 till 55 years as a result of clinical inspection, agree ICD-10, have been revealed sexual infringements F52.0 "Absence or loss of a sexual inclination" (37,5%), F52.10 "Sexual disgust" (21,9%), F52.11 "Absence of sexual satisfaction", including sexual anhedonia (28,1%), F52.7 "Increased sexual inclination" (12,5%) in frameworks F21 "Shizotypal frustration" (46,9%), F60 "Specific frustration of the person" (22,8%), F4 "Neurotic, connected with stress and? ?? ?? ?? ?? ?? ?? frustration" (16,7%), F0 "Organic, including symptomatic, mental frustration" (15,6%).

As frustration of a sexual inclination at researched patients has been caused by mental infringements, as conducting (leading) methods in medical - rehabilitation actions has been elected psychopharmaco-and psychotherapy.

## T09-P-08

### Can sexual dysfunctions lead to substance abuse disorders?

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