European Journal of Obstetrics & Gynecology and Reproductive Biology 211 (2017) 199–209

Contents lists available at ScienceDirect

European Journal of Obstetrics & Gynecology and Reproductive Biology

journal homepage: www.elsevier.com/locate/ejogrb

Oral Abstracts, 9th EUGA Annual Congress, Leading lights in Urogynecology in Amsterdam, Holland, 03–05 November 2016

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Urge 1 Study – A randomized cross-over clinical trial to compare medical treatment of urgency urinary incontinence with surgical treatment

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Introduction: It is believed that urgency urinary incontinence (UUI) is caused by detrusor hyperactivity. Solifenacin is considered as a first-line standard medical treatment. However, after repair of vaginal prolapse by a bilateral replacement of the uterosacral ligaments and a repair of the anterior compartment 90% of patients with UUI were cured. Since UUI symptoms were identical in patients with less prolapse we considered that also minor defects of the vaginal apical holding apparatus could lead to UUI. Unilateral apical vaginal fixation did not lead to cure, therefore a bilateral replacement of the USL by cervico-sacropexy (CESA) or vagino-sacropexy (VASA) was developed.

Methods: Women with UUI without genital prolapse were eligible for this study (ClinicalTrails.gov Identifier: NCT01737411). UUI symptoms were assessed as usual. Patients were randomized either to 10 mg solifenacin for 4 months or to surgery (CESA or VASA). The surgical procedures of CESA and VASA had been published and described in detail (www.cesa-vasa.com).

Cure was defined by the following: voiding frequency <8 times/day, no involuntary leakage of urine and no stress urinary incontinence. After 4 months the still incontinent women received the treatment of the other arm.

Results: 77 patients were evaluable for analysis. In total, after primary solifenacin treatment 3 out of 58 patients (5%) were cured. After primary CESA or VASA surgical treatment 16 out of 40 patients (40%) were cured of their UUI symptoms. After cross-over one was cured by solifenacin of the 21 who failed surgery, however, 10 patients of 25 (40%) who failed solifenacin became continent. Therefore, the overall cure rate was 5% for solifenacin and 40% for the surgery ($p = <0.001$).

Conclusions: The CESA and VASA surgical procedures provide a causal therapy in the treatment of involuntary urinary leakage.

http://dx.doi.org/10.1016/j.ejogrb.2017.01.027

0301-2115/

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Persistence and adherence with mirabegron versus antimuscarinics in overactive bladder: retrospective analysis of a UK General Practice Prescription Database

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Introduction and aim of the study: Antimuscarinics (AMs) for overactive bladder (OAB) treatment are generally associated with poor persistence [1,2]. The study objective was to investigate persistence with the beta-adrenoceptor agonist mirabegron (MIR).

Materials and methods: Retrospective cohort analysis of a UK longitudinal GP prescription database. Patients were aged ≥18y, initiated OAB monotherapy in the 6 months to 31/05/2014, and were in the database ≥12 months before and after the start date. 'Persistence' was defined as time-to-discontinuation, with a 30-day grace period.

Results: The total cohort included 6189 patients (34% male, mean age 63.8y). Compared with AMs, MIR patients ($n = 379$) were more likely to be treatment-experienced (45.6% vs 4.7–27.1%) and be taking more concomitant medication classes (mean 8.9 vs 5.4–7.5). MIR was associated with a longer median time-to-discontinuation (Fig. 1), greater persistence at 12 months (24% vs 10–19%), and a significantly lower risk of discontinuation in univariate and multivariate analyses ($p < 0.01$ vs each AM). Adherence was significantly greater with MIR vs AMs (mean medication possession ratio 48% vs 28–40%, $p < 0.001$).

Interpretation of results: MIR was associated with better persistence than AMs. The decline in persistence with all drugs after