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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.

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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

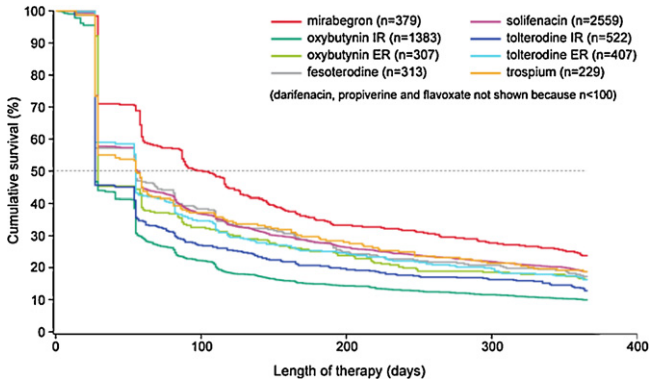

Fig. 1. Median time to discontinuation of mirabegron and antimuscarinics (cumulative survival, %).

1 month underlines the importance of early follow-up and counselling.

Conclusions: MIR gave a longer time-to-discontinuation and significantly better persistence than AMs.

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Long-term satisfaction rate of two different trans-obturator techniques for surgical treatment of women with urinary incontinence: a randomized study follow-up

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Introduction and aim of the study: We performed a follow-up of our 2007 randomized study in which we compared short-term results of the inside-out (TVT-O) and the outside-in (Monarc) trans-obturator techniques for treatment of women with SUI/MUI in order to evaluate the long-term results of both methods.

Materials and methods: Women ($N = 120$) who participated in primary study were included. History, gynecological examination, POP-Q, ultrasound, Q-tip test, pad test, and uroflowmetry were performed. Urinary culture was obtained in symptomatic patients. SPSS Statistics Programme 21.0 was used for the analysis. Descriptive statistics were calculated on basic patients' characteristics. We used non-parametric tests for numerical data comparisons between/within groups and Pearson's Chi-square to compare categorical data between groups. Statistical significance was set at $p < 0.05$.

Results: 92/114 women (6 passed away) responded (80.7%), 52 underwent Monarc and 40 TVT-O. Average time from the operation was 10.2 ± 0.6 years. There was no difference in basic patients' characteristics, Q-tip test, pad test, and uroflowmetry results between both groups. Average satisfaction rate (scale 0–100%) in the original study was $90.6 \pm 14.8\%$ and $81.3 \pm 29.3\%$ at the check-up ($p = 0.03$). For Monarc, satisfaction rates were $90.1 \pm 16.1\%$ and $83.3 \pm 27.8\%$ ($p = 0.185$), and for TVT-O $91.4 \pm 13.2\%$ and $78.2 \pm 31.2\%$ ($p = 0.007$), respectively. There was no difference in the follow-up satisfaction rates between groups ($p = 0.301$). No vaginal tape erosions were found and 88.4% of patients had negative stress pad test. 22.8% of patients had positive urinary cultures and these patients had lower satisfaction rates than others ($64.9 \pm 36.2\%$ versus $86.2 \pm 25.3\%$, $p < 0.001$).

Interpretation of results: According to our results, both procedures seem to be equally successful. Satisfaction rate was ≥80% in 79.3% of patients. Only one patient required another anti-incontinence procedure. Some cases of lower success rate could be the consequence of underlying bladder infection and/or co-existing OAB symptoms.

Conclusions: There is high 10-year satisfaction rate with both procedures.

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Tolerability, efficacy and durability of response of intravesical injection of botulinum toxin type a into detrusor muscle I

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Introduction and aim of the study: In this ongoing prospective, non randomized, ongoing study we evaluated the Tolerability, efficacy and durability of response of intravesical injection of botulinum toxin type A into detrusor muscle in patients with refractory idiopathic detrusor overactivity using flexible cystoscopy under local anesthesia.

Materials and methods: A total of 43 patients with a mean age of 35 women and 8 men with a mean age of 62 years (range 25–84) with refractory idiopathic detrusor overactivity (IDO) were all treated with injections of 100–200 units of botulinum toxin A ® (Allergan Inc., Irvine, CA, USA) into the bladder with the guidance of a flexible cystoscopy. All the patients completed a micturition diary and had both urinalysis and urodynamics (pressure-flow studies) before treatment. The severity of symptom was quantified using the ICS OAB questionnaire. This was completed pre-procedure and at six weeks afterwards. Pain score was evaluated with the 0-10 Numeric Pain rating Scale immediately after the procedure. Post micturition urine volume was measured six weeks after the procedure.

Results: After six weeks 84% of the patients reported a reduction in symptom score by 4 points or more (range −4 to −16); 11. 4% reported no change in symptom score and 4.6% patients reported a worsening of symptom score by 2 points (+2). Mean reduction in OAB score was −4.3. There was significant reduction in urgency ($p < 0.00001$). The Mean pain score was 3.5 (range 0–8).

Interpretation of results: Botulinum toxin-A using flexible cystoscopy was well tolerated and demonstrated significant and clinically relevant improvements in all (IDO) symptoms.

Conclusions: Intradetrusor botulinum toxin-A injection using and flexible endoscopy is a well tolerated and effective procedure to manage patients with refractory (IDO) in an office setting.

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