Original Article: European Men’s Health Report
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Abstract ID: #0126

ERECTILE DYSFUNCTION TREATMENT AS A MEANS TO IMPROVE MEDICATION ADHERENCE AND COMORBIDITY MANAGEMENT

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Background: The high prevalence of ED associated with antidepressants (i.e., SSRIs), antihypertensives (i.e., thiazide diuretics and β-blockers), and antipsychotics (i.e., thioridazine) contributes to low treatment adherence, which can compromise optimal therapeutic effect.

Materials & Methods: Published literature was reviewed to explore the concept that effective ED treatment with phosphodiesterase 5 inhibitors can improve adherence to medications with sexual side effects and improve overall patient management.

Results: Published studies support the effectiveness of ED treatment with sildenafil in men taking antihypertensives. In men taking antipsychotics, and in men with antidepressant-induced ED. Sildenafil improves adherence to other medications, as shown by retrospective claims database analysis of men non-adherent to antidepressants, antihypertensives, or an oral hypoglycemic or antihyperlipidemic. Treatment of ED may promote active comorbidity management, as shown by a retrospective cohort study of hypertensive men over a 7 year period, in which ED treatment (sildenafil in 99% of cases) was associated with improved blood pressure management. An economic modeling study in patients taking antidepressants showed that sildenafil add-on therapy may be a cost-effective alternative to discontinuing, switching, or adding another antidepressant treatment.

Conclusion: Medication adherence is important for avoiding negative clinical outcomes associated with chronic diseases such as depression and hypertension. Non-adherence to medications that are associated with causing ED (e.g., antidepressants, antihypertensives, and antipsychotics) may increase related health care costs as well as lead to greater morbidity and mortality. Concomitant ED treatment may promote medication adherence and better disease management, which has been shown to be cost effective.

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ERECTILE FUNCTION, ERECTION HARDNESS, AND TOLERABILITY IN MEN TREATED WITH VIAGRA® (SILDENAFIL CITRATE) 100 MG VERSUS 50 MG FOR ERECTILE DYSFUNCTION

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Background: The efficacy and tolerability of VIAGRA® (sildenafil citrate) for treating erectile dysfunction (ED) have been well established in clinical trials, most of which administered Viagra on demand as a flexible-dose: 50 mg initially with adjustment to 25 mg or 100 mg depending on toleration and efficacy. However, an initial dose of 100 mg may be the best choice, except in men for whom it is inappropriate, because it would reduce the need for titration and could prevent discouragement and treatment discontinuation should 50 mg be insufficient for optimal efficacy.

To answer this question, the manufacturer’s database of double-blind placebo-controlled trials of Viagra in the treatment of ED was used to compare efficacy and tolerability between treatment with 50 mg and 100 mg doses.

Materials & Methods: Results for erectile function (using the Erectile Function domain of the International Index of Erectile Function (IEF-EF) were available from 5 fixed-dose trials (>1500 men) and pooled from two of these that had a similar design (>500 men). Results for erection hardness Erection Hardness Score (EHS) were available and pooled from 2 fixed-dose trials of similar design (>500 men). Tolerability data were available and collated from all 74 flexible- and fixed-dose trials in the database (>16,000 men).

Results: The improvement in the IIEF-EF score from baseline after 8 – 12 weeks of treatment was consistently greater in the 100-mg versus 50-mg group across the 5 trials and was significant when data from the 2 trials with similar design were pooled (10.7 ± 0.64 vs. 8.9 ± 0.63, P=0.0287). During the first 2 weeks of treatment, the odds (OR) of achieving EHS4 erections (completely hard and fully rigid) were almost doubled for the 100-mg vs. 50-mg group in one of 2 trials (OR = 1.77, P=0.0398). Sildenafil was well tolerated at a dose of 50 or 100 mg in these fixed-dose trials and overall.

Conclusion: Men with ED treated with Viagra 100 mg compared with 50 mg may be more likely to achieve a greater improvement in erectile function and, within the first 2 weeks, completely hard and fully rigid erections, with no greater risk of intolerability.

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Abstract ID: #0137

ERECTILE DYSFUNCTION SHOCK WAVE THERAPY, A NEW MODALITY IN THE MANAGEMENT OF ERECTILE DYSFUNCTION: DOES IT IMPROVE THE OUTCOME?

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Background: Erectile dysfunction shockwave therapy (EDSWT) has brought new hope in the management of erectile dysfunction (ED). Its role in the treatment of ED has not been established to date, however its application in different medical disciplines, owing to its property of neovascularisation, has proved its worth. Our objective was to evaluate the efficacy of EDSWT on men with ED and to analyze its role in the management of ED.

Materials & Methods: We conducted a double-blind randomized placebo-controlled study. A total of 60 patients diagnosed as having arteriogenic ED who had International Index of Erectile Function ED (IIEF-ED) domain scores between 3 and 18 (average = 7.85) and abnormal nocturnal penile tumescence (NPT) parameters were enrolled for the study. Follow-up assessments using the IIEF-ED questionnaire and Doppler ultrasound examinations were done at 3 and 6 month periods.

Results: We evaluated 60 middle-aged men (average age = 39.2 years) with arteriogenic ED (mean duration of 2.08 years). At 6 months' follow-up, significant increases in IIEF-ED domain scores were recorded in all men (23.30 ± 3.37 vs. 7.85 ± 2.56, P < 0.001). Significant increases in the duration of erection and penile rigidity were also recorded. Doppler ultrasound study objectively recorded the improvement in various parameters. No adverse events were noted during follow-up.

Conclusion: This treatment modality has shown promising results in its efficacy for the improvement of erectile function and the fact that the effects were natural, long-lasting and provided measurable improvement gives hope for the attainment of a possible cure for ED.

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Abstract ID: #0103

Topic: Urology/Genitourinary Oncology

FLUORESCENCE IN-SITU HYBRIDISATION (FISH) – IS IT USEFUL FOR DETECTING UROTHELIAL CANCER IN AT RISK PATIENTS?

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Background: The multi-target fluorescence in situ hybridisation (FISH) probe set UroVysion, containing probes to chromosomes 3, 7 and 17, and 9p21 band, claims to have high sensitivity and specificity for detecting urothelial carcinoma and dysplasia. The aim of this study was to deter-

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mine the accuracy of the Urovysion FISH test in detecting urothelial carcinoma or dysplasia in patients who presented with haematuria or a past history of urothelial cancer.

**Materials & Methods:** Between January 2004 and December 2010, 627 urine samples were tested using Urovysion and were reviewed retrospectively. Indication for Urovysion tests were patients with haematuria and/or past history of urothelial cancer in remission and those on follow-up. The Urovysion FISH test was done prior to the endoscopic biopsies. Bladder or ureteroscopic mucosal biopsies were done and the histopathological findings were reported by a trained pathologist. A FISH result was considered as positive if there was polyplody in chromosomes 3, 7 and 17 or a deletion in chromosome 9p21.

**Results:** 260 patients underwent the Urovysion FISH test and cystoscopic or ureteroscopic examination and biopsies. Mean age was 56.3 years (range 23-84). 185 (71.2%) were men. 71 Urovysion FISH tests were positive, of which 13 were found to have transitional cell carcinoma (TCC) of the bladder, seven had upper tract TCC and 13 dysplasia of the bladder mucosa. There were 37 false-positive and four false-negative Urovysion FISH tests. The sensitivity and specificity of the Urovysion FISH test were 89.2% and 83.4%, respectively. The positive (IPV) and negative predictive values (NPV) were 47.1% and 97.9%, respectively. By excluding patients who had positive detection of chromosome 9, we improved the accuracy of the screening test to: sensitivity 86.6%; specificity 96.4%; PPV 75.9% and NPV 97.9%.

**Conclusion:** The Urovysion FISH test shows high specificity and negative predictive value for detecting urothelial cancer. Urovysion FISH test may be useful in the evaluation of patients at risk of urothelial cancer.

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**Abstract ID: #0093**

**CLINICAL UTILITY OF NMP22 FOR THE SURVEILLANCE OF PATIENTS WITH RECURRENT BLADDER CANCER: A MULTI-CENTER CROSS-SECTIONAL STUDY**

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**Background:** To employ decision curve analysis to determine the impact of NMP22 on clinical decision-making for the surveillance of bladder cancer patients using data from a prospective trial.

**Materials & Methods:** The study included 668 patients with a history of non-muscle-invasive bladder cancer who underwent cystoscopy, urine cytology, and measurement of urinary NMP22 levels. We constructed several prediction models to estimate risk of bladder cancer. The base model was generated using patient characteristics (age, gender, race, and history of intravesical therapy); cystology and NMP22 were added to the base model to determine effects on predictive accuracy. Clinical net benefit was calculated by summing the benefits and subtracting the harms and weighting these by the threshold probability at which a patient or clinician would opt for cystoscopy.

**Results:** 97 patients were found to have recurrence of bladder cancer (14.5%). In univariable analyses, NMP22 was the strongest predictor of bladder cancer presence (predictive accuracy of 66.0%), followed by cystology (56.5%) and history of intravesical therapy (56.4%). In multivariable prediction models, NMP22 improved the predictive accuracy of the base model by 11.5% (AUROC = 59.2-70.7%, P = 0.0001) and that of the base model plus cystology by 6.4% (AUROC = 64.3-70.7%, P = 0.036). Decision curve analysis revealed that adding NMP22 to other models increased clinical benefit, particularly at higher threshold probabilities.

**Conclusion:** NMP22 is a strong, independent predictor of bladder cancer in patients undergoing surveillance. Addition of NMP22 improves the accuracy of standard predictors by a statistically and clinically significant margin. Decision curve analysis suggests that integration of NMP22 into clinical decision-making helps spare unnecessary cystoscopies, with minimal increased risk of missing a bladder cancer recurrence.

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**Abstract ID: #0091**

**PREDICTING CLINICAL OUTCOMES AFTER RADICAL NEPHROURETERECTOMY FOR UPPER TRACT UROTHELIAL CARCINOMA**

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**Background:** We tested the prognostic value of pathologic characteristics and developed models to predict the individual probabilities of recurrence-free survival (RFS) and cancer-specific survival (CSS) after radical nephroureterectomy (RU) for upper tract urothelial carcinoma (UTUC).

**Materials & Methods:** Our study included 2244 patients treated with RU without neoadjuvant or adjuvant therapy at 23 international institutions. Tumor characteristics included T classification, grade, lymph node status, lymphovascular invasion, architecture, location, and concomitant CIS. The cohort was split for development (12 centers, n = 1373) and external validation (11 centers, n = 971).

**Results:** At a median follow-up of 45 months, 501 patients (22.3%) experienced disease recurrence and 418 patients (18.6%) died of UTUC. On multivariable analysis, T classification (P - trend < 0.001), lymph node metastasis (HR: 1.98, P = 0.002), lymphovascular invasion (HR: 1.66, P = 0.001), and sessile architecture (HR: 1.76, P = 0.001), and concomitant CIS (HR: 1.33, P = 0.035) were associated with disease recurrence. Similarly, T classification (P - trend < 0.001), lymph node metastasis (HR: 2.23, P = 0.001), lymphovascular invasion (HR: 1.81, P = 0.001), and sessile architecture (HR: 1.72, P = 0.001) were independently associated with cancer-specific mortality. Our models achieved 76.8% and 81.5% accuracy for predicting RFS and CSS, respectively. In contrast to these well-calibrated models, stratification based upon AJCC stage grouping resulted in a large degree of heterogeneity and did not improve discrimination.

**Conclusion:** Using standard pathologic features, we developed highly accurate prognostic models for the prediction of RFS and CSS after RU for UTUC. These models offer improvements in calibration over AJCC stage grouping and can be utilized for individualized patient counseling, follow-up scheduling, risk stratification, and treatment planning.