THE JOURNAL of UROLOGY®

1256

STUDIES WITH TRIMIX GEL IN MEN WHO FAILED PHOSPHODIESTERASE INHIBITORS

Joel L Marmar, Thomas J Harkins, John Riordan. Camden, NJ, and Cherry Hill, NJ.*

INTRODUCTION AND OBJECTIVE: Trimix (papaverine, phentolomine and PGE1) has been prepared by compounding pharmacists and used for intracavernous injections. After mixing, the shelf life is limited and refrigeration is recommended. As an alternative, topical Trimix gel seemed more stable and easier to use, but the results were poor due to limited absorption. Recently, we evaluated a new Trimix gel for administration at the urethral meatus. In this report, Erection Hardness Scores (EHS) and penile rigidity studies were recorded after the gel on 42 men with mixed morbidities who failed with PDE5 oral agents.

METHODS: Sixteen men were on anti hypertensive meds, 12 had type II diabetes,8 had high cholesterol and 6 were post radical prostatectomy. Ten men had co morbidies. Prior to the gel, an (EHS) was recorded for the experience with oral agents. The Trimix active ingredients and 0.3 ml of gel were maintained in separate interlocking syringes at room temperature until the time of use. The final preparation was completed by vigorous mixing between the interlocking syringes. The mixed gel was inserted painlessly into the urethral meatus, and the patient massaged the outer glans for 2 minutes to promote absorption. There was no other form of stimulation. After the gel, an EHS was recorded for each patient. In addition, 9 had measurement of buckling pressures, and 7 had rigiscans.

RESULTS: For all 42 patients (mean age 55.2 yrs) the EHS was recorded as 1 for the oral agents(penis was larger but not hard), but 22 of these patients actually had no increase in size. After the gel, the mean EHS was 2.2, but 11 pts had an EHS of 3 (26.1%), and 6 had a 4 (16.6%). Thus, 40.4% of the study group had erections that were sufficient for penetration. In those with an ESH of 4, the buckling pressure was >90mm Hg. The 7 rigiscans provided real time information about the gel response and documented some tumescence in all cases. In a comparison of 3 and 4 scores,oral agents vs. gel, X^2= 10.0, df 1, p<0.001.

CONCLUSIONS: Trimix gel may have several advantages over oral agents and intrcavernous injections. The active ingredients and gel may be carried by the patient at room temp. The shelf life is long because the active ingredients are mixed only at the time of use. The interlocking syringes permit thorough mixing. Administration is painless, and message of the glans may enhance mucosal absorption. Even without stimulation by a partner or videos, these patients demonstrated statistically significant greater EHS with gel versus oral agents. These pilot data support the use of Trimix gel for ED, but more prospective trials are needed.

SATISFACTION PROFILES AND THEIR DETERMINANTS IN MEN USING INTRACAVERNOSAL INJECTION THERAPY

Nelson E Bennett, Patricia Guhring, Joseph Narus, John P Mulhall. New York, NY.*

INTRODUCTION AND OBJECTIVE: Intracavernosal injection therapy (ICI) is a well-established treatment strategy for men with erectile dysfunction (ED). Several reports have discussed drop-out rates and the predictors of such attrition. This study was undertaken in men using ICI for at least 6 months to define satisfaction levels and what predicts satisfaction with treatment.

METHODS: Men using ICI completed a baseline IIEF and those that had used ICI for greater than 6 months completed a second IIEF questionnaire at least 6 months after starting ICI. At this time they also had erectile rigidity scored using the erection hardness core (EHS). Patient demographic, comorbidity and prior treatment information was compiled. Patients who had had radical pelvic surgery were excluded. Attention was focused on the satisfaction domains of the IIEF, specifically intercourse satisfaction (Q 6-8; max score 25) and overall satisfaction (Q 13-14; max score 10). Multivariable analysis was performed to define predictors of satisfaction. Pearson correlation coefficient was generated for the correlation between EF domain (EFD) score and satisfaction domains.

RESULTS: 122 men were analyzed. Mean age and duration of ED were 68±32 and 3.6±4.2 years. 10% of men had one vascular comorbidity, 42% two, 36% three and 12% ≥4. Baseline IIEF-EF domain score was 13±12 and this rose to 26±2 after 6 months of ICI (p<0.001). 88% of men used trimix, 7% bimix, 2.5% papaverine and 2.5% PGE1 monotherapy. 62% continued to inject at a mean follow-up time-point of 22±7 months. Baseline satisfaction domain scores were: intercourse satisfaction 5±2; overall satisfaction 4±2.5 (Total 9±4.5). These scores rose to 12 (p<0.01) and 7 (p<0.05) respectively (total 19±4) after ICI treatment. Pearson correlation coefficient between EF and total satisfaction scores was 0.66. Predictors of satisfaction included: increased patient age, partner age and greater levels of erectile rigidity (see Table)

CONCLUSIONS: One third of men cease injection therapy within 2 years of initiation. The predictors of continued use included older patient age, young partner age, a clinically meaningful increase in IIEF-EF domain score and obtaining a fully rigid erection.

Multivariable Analysis of Predictors of Satisfaction with ICI

	OR	95% CI	p Value
Increase >10 years in patient age	2.1	1.1-3.2	<0.01
Decrease >10 years in partner age	2.5	2.0-4.5	<0.01
Increase of ≥6 points on the EFD score	3.1	1.9-6.3	<0.01
Obtaining an EHS 4 (fully rigid) erection	6.8	2.7-9.8	<0.01

Source of Funding: None

1258

IMPROVEMENT IN SEXUAL SATISFACTION OF FEMALE PARTNERS OF MEN WITH PREMATURE EJACULATION (PE) TREATED WITH DAPOXETINE (DPX)

Gerald B Brock, Jacques Buvat, Francois A Giuliano, Stanley Althof, Ridwan Shabsigh, Fisseha Tesfaye, Margaret Rothman, David Rivas. London, ON, Canada, Lille, France, Garches, France, Cleveland, OH, Brooklyn, NY, and Raritan, NJ.*

INTRODUCTION AND OBJECTIVE: Improving partner satisfaction with sexual intercourse is essential to men with PE, and was evaluated with DPX, a PE treatment in development.

METHODS: Data were from an integrated analysis of 2 US phase III trials (N = 2,614) and a worldwide phase III trial (N = 1,162). These double-blind, parallel-group studies randomized men ≥18 years of age, diagnosed with PE based on the DSM-IV-TR criteria, with intravaginal ejaculatory latency time ≤2 min in ≥75% of intercourse episodes, to receive placebo, DPX 30 mg, or DPX 60 mg, on-demand for 12 wks (US trials) or 24 wks (worldwide trial). In the US trials, partners reported their perception of the man's control over ejaculation and their own satisfaction with sexual intercourse at Wks 4, 8, and 12 (5-point scales). In the worldwide trial, partners completed the Premature Ejaculation Profile (PEP) at Wks 4, 8, 12, and 24, including measures of their perception of the man's control over ejaculation and their own satisfaction with sexual intercourse and ejaculation-related personal distress and interpersonal difficulty (5-point scales).

RESULTS: In the US trials, <26% of partners reported "good" or "very good" satisfaction with sexual intercourse at baseline, which increased to 39.1% and 47.4% with DPX 30 mg and 60 mg at Wk 12 (vs 25.3% with placebo; *P* <0.001 for both); similar improvements were reported in perception of the man's control over ejaculation. In the worldwide trial, mean scores on all partner PEP measures were significantly (*P* <0.05 for all) improved with DPX 30 mg and 60 mg vs placebo at all time points from Wk 4 through Wk 24. At baseline, 16% of partners reported "good" or "very good" satisfaction with sexual