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Table of Contents

Board of Directors	9
Committees	10
Local Arrangements	10
Program	10
Prize Essay	10
Public Media	10
Audio Visual	10
Program Abstract Review	11
Ambrose Reed Socioeconomic	11
General Information	12
Social Functions	18
Youth Programs	21
Tours	22
Corporate Patrons/Contributors	25
Convention Floor Plan	29
Exhibit Floor Plan	32
Peabody Floor Plan	34
Omni Rosen Floor Plan	36
Subspecialty Programs	38
Genitourinary Reconstructive Surgeons	38
Society for Pediatric Urology	39
Urodynamics Society	41
Society for the Study of Male Reproduction	43
ICUD/WHO Consultation CA Prostate	44
Society for Basic Urologic Research	45
Society for Urology and Engineering	46
Joint Program of the American Urological Association and the Conferderaçion Americana de Urologia	48
Society for the Study of Impotence	49
Society of Urologic Oncology	51
American Foundation for Urologic Disease Research Scholar Program	52
American Association of Clinical Urologists	54
Meeting Overview	56
Sunday's Sessions	71
Monday's Sessions	129
Tuesday's Sessions	163
Wednesday's Sessions	201
Thursday's Session	235
Office of Education Courses by Date and Time	236
Office of Education Courses by Category	244
Video Forum	255
Video Library	263
1995-1996 AUA Awards	264
Exhibitors Product Category by Listing	266
Exhibitors Product Service by Listing	271
Abstracts	286
Index of Authors/Participants	712
Subject Index of Abstracts	761
Index of Advertisers	787

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736

CLINICAL OUTCOME OF T1 BLADDER CANCER. Miguel Antelo, Colin P. Dinney and H. Barton Grossman, Houston, TX (Presentation by Dr. Antelo)

INTRODUCTION AND OBJECTIVES: Patients with T1 bladder cancer harbor neoplasms with documented invasive potential. We evaluated the therapeutic interventions and clinical outcome in 89 patients with T1 disease.

METHODS: Eligible patients had T1 bladder cancer diagnosed at the University of Texas MD Anderson Cancer Center from August, 1975 through April, 1994 who had follow-up data. 89 patients met these criteria and had a mean and median follow-up of 4.1 and 3.4 years respectively (range 0.9 to 19.9 years). Treatment included transurethral resection, intravesical chemotherapy, BCG, and/or cystectomy.

RESULTS: The mean survival for all 89 patients was 12.6 years. The 5 and 10 year survival rates were 69% and 54% respectively. The rates of recurrence and progression were 40% and 26% respectively. The recurrence and progression rates for 36 patients receiving BCG were 42% and 22% respectively. 35 patients were treated with cystectomy (21 early and 14 delayed). Progression (P) and death from bladder cancer (D) occurred in patients treated with both early (5P, 3D) and delayed cystectomy (7P, 3D).

	# Pts.	Median Survival	Confidence Interval	Bladder Ca Deaths
No Cystectomy	54	8.7 years	7.1 - 10.3	17%
Cystectomy	35	9.8 years	8.9 - 10.7	17%

CONCLUSIONS: Most patients with T1 bladder cancer have a long survival. Cystectomy does not afford protection from progression and death from bladder cancer and does not improve survival. Patients presenting with T1 bladder cancer need careful monitoring with aggressive therapy (cystectomy) reserved for recurrent invasive bladder cancer or disease refractory to local therapy.

Supported in part by grant U01-CA56973 from NCI, NIH.

737

UK-92,480, A NEW ORAL THERAPY FOR ERECTILE DYSFUNCTION, A DOUBLE-BLIND, PLACEBO CONTROLLED TRIAL WITH TREATMENT TAKEN AS REQUIRED

Ian Eardley (Leeds, UK), Robert J Morgan (London, UK), Wallace W Dinsmore (Belfast, UK), Josephine Pearson, Maria B Wulff, Mitraddev Boolell (Sandwich, UK). (Presentation by Mr I Eardley).

INTRODUCTION AND OBJECTIVES

Nitric oxide, via cGMP, is critical for the relaxation of the corpus cavernosum, a key factor in penile erection. UK-92,480 is an orally active potent inhibitor of type V cGMP-specific PDE, the predominant isoenzyme in the human corpus cavernosum and as such has the potential to enhance penile erectile activity. The efficacy and safety of UK-92,480 in improving erectile activity was evaluated in patients with MED without an established organic cause.

METHODS

42 patients with a mean age of 53 years (range 34 - 70) a mean duration of MED of 3 years (range 0.5 - 10) took placebo or UK-92,480 (25, 50 or 75mg) as required for 28 days in a double blind, randomised, two-way, crossover study.

RESULTS

Of the patients with complete efficacy data, 34/37 (92%) reported an improvement in the quality of erections on UK-92,480 compared to 10/37 (27%) on placebo ($p < 0.0001$). This was confirmed by the patients partner: 33/36 (91%) felt that there was an improvement in their partners erection on UK-92,480 compared to 7/36 (19%) on placebo ($p < 0.0001$). The mean number of erections which were sufficiently rigid for penetrative sexual intercourse over 28 days was 18.4 (14 - 24.3, 95% confidence interval) on UK-92,480 compared to 5.6 (4.1 - 7.4) on placebo ($p < 0.0001$). The frequency of use of UK-92,480 was 12.5 doses over 28 days compared to 8.6 for placebo. In general UK-92,480 was well tolerated, the most commonly reported adverse events were headache, dyspepsia and muscle aches

738

UK-92,480, A NEW ORAL TREATMENT FOR ERECTILE DYSFUNCTION: A DOUBLE-BLIND, PLACEBO-CONTROLLED, ONCE DAILY DOSE RESPONSE STUDY. Clive J C Gingell, Bristol, UK; Alain Jardin, Paris, France; Arne M Olsson, Lund, Sweden; Wallace W Dinsmore, Belfast, UK; Ian H Osterloh, John Kirkpatrick, Michelle Cuddigan, Sandwich, UK; and the Multicentre Study Group. (Presentation by Dr Gingell).

INTRODUCTION: It is now recognised that penile erection is mediated by the action of nitric oxide/cGMP (cyclic guanosine monophosphate). UK-92,480 is a selective inhibitor of Type 5 phosphodiesterase, the predominant isoenzyme causing breakdown of cGMP in the human corpus cavernosum.

METHODS: This trial (protocol 148-353) recruited 351 male patients (mean age 53, range 24-70 years) with erectile dysfunction (ED) of no known organic cause. After a 2-week run-in on no treatment, patients were randomly allocated to receive oral capsules of 10mg, 25mg or 50mg of UK-92,480 or double-blind placebo administered once daily for 28 consecutive days. Efficacy instruments included patient assessment of whether treatment improved erections, a 15-item self-administered sexual function questionnaire (SFQ), and diary records of erections.

RESULTS: The proportions of patients reporting that treatment had improved their erections were 38% (placebo), 65% (10mg), 79% (25mg) and 89% (50mg) (p for treatment effect < 0.001). SFQ analyses showed similar dose-response relationships for frequency, hardness and duration of erections ($p < 0.001$) and other parameters of sexual function including number of satisfactory intercourses and quality of sex life.

UK-92,480 treatment was generally well-tolerated. Headache, flushing, dyspepsia and muscle aches were reported more times than other adverse events. The overall proportion of patients discontinuing treatment because of adverse events was less than 5% and the proportions were similar for all treatment groups.

CONCLUSIONS: The results indicate that UK-92,480 is an effective, well-tolerated, oral treatment of ED in patients with no known organic cause.

739

UK-92,480, A NEW ORAL TREATMENT FOR ERECTILE DYSFUNCTION. A DOUBLE-BLIND, PLACEBO CONTROLLED CROSSOVER STUDY DEMONSTRATING DOSE RESPONSE WITH RIGISCAN AND EFFICACY WITH OUTPATIENT DIARY. Mitraddev Boolell (Sandwich UK), Sam Gepi-Attee & Clive Gingell (Bristol UK) and Michael Allen (Sandwich UK) (Presented by Clive Gingell).

INTRODUCTION AND OBJECTIVES: Male erectile dysfunction (MED) is a common condition for which there is no satisfactory oral therapy. Recent studies suggest that erection is dependent on nitric oxide and its second messenger, cyclic guanosine monophosphate (cGMP). UK-92,480 is a potent selective inhibitor of type 5 (cGMP-specific) phosphodiesterase, the predominant isoenzyme in the human corpus cavernosum. UK-92,480 was evaluated in patients with MED without an established organic cause.

METHODS: 12 patients entered a double blind randomised placebo controlled crossover study. In the first phase (4-way crossover) efficacy was evaluated by the duration of penile rigidity (RigiScan) during 2 hours of visual sexual stimulation following single doses of UK-92,480 (10mg, 25mg, 50mg and placebo). In the second phase (2-way crossover) efficacy was assessed by a diary record of erectile activity following daily doses of UK-92,480 (25mg) and placebo for 7 days.

RESULTS: Mean duration of rigidity $> 80\%$ (in minutes) at the base of the penis was 1.3 (95% confidence interval, 0.4-3.1) on placebo, 3.5 (1.6-7.3) on 10mg ($p=0.095$), 8.0 (3.7-16.7) on 25mg ($p=0.003$), and 11.2 (5.6-22.3) on 50mg ($p=0.0004$). Corresponding values at the tip of the penis were 1.2 (0.4-2.7) on placebo, 4.6 (2.4-8.5) on 10mg ($p=0.014$), 6.9 (3.5-13.1) on 25mg ($p=0.002$), and 7.4 (3.9-13.4) on 50mg ($p=0.001$). From the diary, the mean number of erections of sufficient rigidity for penetrative sexual intercourse was 6.1 (3.2-11.4) on UK-92,480 and 1.3