162

SEXUAL PERCEPTIONS LEADING TO RISKY SEXUAL PRACTICES AMONG THE GERIATRICS IN IBADAN, NIGERIA

Odor King

Dept of Health Promotion and Education, Faculty of Public Health College of Medicine, University of Ibadan Nigeria
E-mail address: odorking001@yahoo.com.

Background: Most studies on sexual behaviours in Africa especially Nigeria focus on young people and adults with limited attention paid to elderly people. There is dearth of information on geriatric reproductive health challenges and involvement in risky sexual activities. This study determined the need for SRH appraisal among Geriatrics in Nigeria.

Methodology: The study was descriptive and cross sectional in design. 400-geriatrics aged 65 years and above were selected using a three-stage sampling technique. Validated questionnaire was designed from six Focus Group Discussions (FGDs) findings. The FGDs and questionnaires data were analysed using thematic approach and descriptive/Chi-square statistics respectively.

Findings/Results: The participants' mean age was 71.8 years. Slightly more than half, (50.5%) were males. A total of 25% of the participants had extramarital sex since they attained 65 years. Among this subgroup, very few (6.8%) used condom. More males (5.3%) than females (1.5%) used condom during the episode ($p < 0.05$). Low condom-use was attributed to the belief that condom is unnecessary (34.5%) and the perception (50%) condom is not for the elderly. Majority (68.8%) was of the view that having sex with virgin could boost their immunity against STI/HIV; which comprised 65.1% males and 34.9% females. Majority of the males (56.4%) and females (66.7%) agreed that engagement in sex has a healing effect on the elderly.

Conclusion/Policy Implications: Appreciable proportion of the elderly was involved in risky sexual activities, while majority's perceptions about Sexual behaviour were negative. Therefore, there is need for appraisal of elderly sexual needs including scaling-up of SRH services to address the problem.

doi:10.1016/j.jomh.2009.08.159

163

IPSS AND QMAX RESPONDERS WITH DUTASTERIDE PLUS TAMSULOSIN: 4-YEAR RESULTS FROM THE COMBAT STUDY

Vincenzo Mirone[1,*], Olivier Haillot[2], Alberto Budía[3], Mark Speakman[4], Betsy Morrill[5], on behalf of the CombAT Study Group

[1] *Università Federico II di Napoli, Napoli, Italy*, [2] *Service d'Urologie, CHU, Tours CEDEX, France*, [3] *La Fe University Hospital, Valencia, Spain*, [4] *Taunton and Somerset NHS Trust, UK*, [5] *Department of Biostatistics, GlaxoSmithKline, NC, USA*
E-mail address: mirone@unina.it (V. Mirone).

Background: 4-year analyses of the CombAT study (n = 4844) showed that dutasteride plus tamsulosin was associated with a significantly lower incidence of acute urinary retention (AUR) or surgery related to benign prostatic hyperplasia (BPH) compared with tamsulosin, and significantly reduced the risk of BPH clinical progression compared with either monotherapy (nominal significance vs dutasteride). Here we present a 4-year analysis of International Prostate Symptom Score (IPSS) responders and peak urinary flow (Qmax) responders in CombAT.

Methods: Following screening, eligible subjects entered a single-blind run-in period during which they received dutasteride and tamsulosin placebos for 4 weeks. All subjects were then randomised to receive 0.5 mg dutasteride, 0.4 mg tamsulosin or the combination once daily for 4 years. The primary endpoint for the 4-year analysis was time to AUR or BPH-related surgery. Secondary endpoints included the proportion of men with an improvement in IPSS from baseline of ≥25%, ≥2 units or ≥3 units (IPSS responders); and an improvement in Qmax from baseline of ≥30% or ≥3 mL/s (Qmax responders).

Results: The proportion of men with a ≥25% IPSS improvement at month 48 was 67%, 61% and 52% in the combination, dutasteride and tamsulosin groups, respectively ($p < 0.01$ for combination vs each monotherapy). The proportion of men with an IPSS improvement ≥3 units was 71%, 66% and 59% in the combination, dutasteride and tamsulosin groups, respectively ($p < 0.01$ for combination vs each monotherapy). For the ≥2 unit category, the proportion of responders was 76%, 72% and 64% in the combination, dutasteride and tamsulosin groups, respectively ($p < 0.001$ for combination vs tamsulosin). Also at month 48, 39% and 40% of men (≥30% and ≥3 mL/s criteria, respectively) in the combination group were Qmax responders; the corresponding proportions in the dutasteride group were 37% and 36%, and in the tamsulosin group were 28% and 26%. The proportions of Qmax responders using both criteria were significantly ($p < 0.001$) higher in the combination group compared with the tamsulosin group, with no significant differences between the combination and dutasteride groups.

Conclusions: At 4 years, combination therapy with dutasteride plus tamsulosin resulted in significantly more IPSS responders (≥25% category) compared with either monotherapy, and significantly more Qmax responders (both categories) than tamsulosin monotherapy.

doi:10.1016/j.jomh.2009.08.160

164

EFFECT OF DUTASTERIDE ON THE DETECTION OF PROSTATE CANCER IN MEN WITH BENIGN PROSTATIC HYPERPLASIA IN THE COMBINATION OF AVODART AND TAMSULOSIN (COMBAT) TRIAL

C.G. Roehrborn[1], A. Tubaro[2,*], J. Barkin[3], T.H. Wilson[4], R.P. Gagnier[5], R. Castro[5], R.S. Rittmaster[5], on behalf of the CombAT Study Group

[1] *Department of Urology, UT Southwestern Medical Center, Dallas, Texas*, [2] *Sant' Andrea Hospital, University of Rome, Rome, Italy*, [3] *Department of Urology, University of Toronto, Toronto, Ontario, Canada*, [4] *Biostatistics and Programming, GlaxoSmithKline, Research Triangle Park, NC, USA*, [5] *Clinical Development, GlaxoSmithKline, Research Triangle Park, NC, USA*
E-mail address: andrea.tubaro@tin.it (A. Tubaro).

Objectives/Background: The REDUCE prostate cancer risk reduction study showed a significant 23% reduction in PCa incidence and improved utility of PSA in detecting PCa, especially high-grade PCa, in men with an elevated PSA and a negative prostate biopsy at baseline, all of whom were rebiopsied after 2 and 4 years. The 4-year CombAT BPH study provides an opportunity to translate the significance of these results to men undergoing annual PSA and DRE screening, in whom all prostate biopsies were for-cause.

Methods: CombAT was a 4-year, double-blind, parallel-group study in men with moderate-to-severe BPH, age ≥50, IPSS ≥12, prostate volume ≥30 cc and serum PSA 1.5—10 ng/mL, who were randomized to receive dutasteride 0.5 mg/day (n = 1623), tamsulosin 0.4 mg/day (n = 1611), or the combination (n = 1610) for 4 years. PSA and DRE were assessed annually, and prostate biopsies were performed on a for-cause basis, based on investigator's clinical judgment.

Results: The cumulative incidence rate of PCa over 4 years was significantly lower in the combination therapy group (2.2%) than in the tamsulosin group (3.8%, $p < 0.01$), and similar to that in the dutasteride group (2.5%), with an overall risk reduction of 37% in the dutasteride arms. Reduced PCa incidence was evident across Gleason grades: of grade ≤6 PCa-positive biopsies, 19/60 were in the combination group, 17/60 with dutasteride, and 24/60 with tamsulosin; among grade 7 the rates were 7/35, 13/35, 15/35 and amung grade 8—10 the rates were 5/20, 6/20, 9/20 for combination, dutasteride, and tamsulosin respectively.

Fewer patients underwent needle biopsy in the combination (110/1610, 6.8%) and dutasteride (137/1623, 8.4%) groups than in the tamsulosin group (208/1611, 12.9%). Of the biopsies performed, 29% were positive for PCa in the combination group, *vs.* 28% (dutasteride) and 24% (tamsulosin).

Conclusion: PCa and biopsy rates were lower in men receiving dutasteride in combination with tamsulosin *vs.* tamsulosin alone. Consistent with the increased utility of PSA for PCa detection demonstrated in the REDUCE study, men receiving dutasteride with or without tamsulosin in CombAT had fewer biopsies, however the diagnostic yield of the biopsies that were performed was slightly higher (number of positive biopsies out of the total number of biopsies performed) *vs.* men receiving tamsulosin. In men who received dutasteride, the reduction in PCa was evident across Gleason grades.

doi:10.1016/j.jomh.2009.08.161

165

EFFECTS OF COMBINATION THERAPY WITH DUTASTERIDE AND TAMSULOSIN ON CLINICAL OUTCOMES IN MEN WITH SYMPTOMATIC BENIGN PROSTATIC HYPERPLASIA: FOUR-YEAR RESULTS FROM THE COMBAT STUDY

C.G. Roehrborn[1,*], J. Barkin[2], P. Siami[3], A. Tubaro[4], R. Damião[5], R.P. Gagnier[6], R. Castro[6], B. Morrill[6], I. Nandy[6], F. Montorsi[7], on behalf of the CombAT Study Group

[1] *Department of Urology, UT Southwestern Medical Center, Dallas, Texas, USA*, [2] *Department of Urology, University of Toronto, Toronto, Ontario, Canada*, [3] *Welborn Clinic, Evansville, Indiana, USA*, [4] *Sant' Andrea Hospital, University of Rome, Rome, Italy*, [5] *Serviço de Urologia, Hospital Universitário Pedro Ernesto — UERJ, Rio de Janeiro, Brazil*, [6] *Research and Development, GlaxoSmithKline, Research Triangle Park, North Carolina, USA*, [7] *Department of Urology, Universita Vita Salute San Raffaele, Milan, Italy*
E-mail address: claus.roehrborn@utsouthwestern.edu (C.G. Roehrborn).

Background: The CombAT study investigated the effect of combination therapy with dutasteride and tamsulosin compared with each monotherapy on symptoms and long-term clinical outcomes in men with moderate-to-severe lower urinary tract symptoms associated with BPH. Here we present the long-term clinical outcomes, symptom changes and clinical progression over 4 years.

Methods: CombAT was a 4-year, multicenter, double-blind, parallel group study in 4844 men ≥50 years with BPH (IPSS ≥12, prostate volume [PV] ≥30 cc, serum PSA 1.5—10 ng/ml, Q_{max} 5—15 ml/s), who were randomised to daily tamsulosin 0.4 mg, dutasteride 0.5 mg, or the combination. The 4-year primary endpoint was time to first AUR or BPH-related surgery. Secondary endpoints included BPH clinical progression; changes in IPSS, Q_{max} and PV; and safety.

Results: The crude incidence rate of AUR or BPH-related surgery was significantly lower (4.2%) in the combination group *vs.* tamsulosin (11.9%, $p < 0.001$), and numerically lower *vs.* dutasteride (5.2%, $p = 0.18$), as was the rate of clinical progression (12.6% *vs.* 21.5% [$p < 0.001$], and 17.8%). Combination treatment reduced the relative risk of AUR or BPH-related surgery by 65.8% (95% CI: 54.7%, 74.1%) *vs.* tamsulosin.

Adjusted mean change in IPSS from baseline to Year 4 was -6.3 points for combination therapy *vs.* -5.3 points ($p < 0.001$) for dutasteride and -3.8 points ($p < 0.001$) for tamsulosin, maintaining the superiority previously reported for month 3 *vs.* dutasteride and month 9 *vs.* tamsulosin.

Overall adverse event (AE) rates or serious drug-related AEs did not differ between treatment groups. Drug-related AEs were more common with combination (28%) *vs.* dutasteride (21%) or tamsulosin (19%); withdrawal due to drug-related AEs did not differ (6%, 4%, 4%, respectively).

After 4 years, incidence of the composite term cardiac failure in the combination group (14/1610, 0.9%) was higher than in either monotherapy: dutasteride 4/1623 (0.2%), tamsulosin 10/1611 (0.6%). The relative risk estimate for time to first cardiac failure event was 3.57 (95% CI: 1.17, 10.8) for combination therapy compared to dutasteride monotherapy and 1.36 (95% CI: 0.61, 3.07) compared to tamsulosin monotherapy. No causal relationship between dutasteride (alone or in combination with an α-blocker) and cardiac failure has been established.

Conclusions: In the CombAT study, the risk of AUR or BPH-related surgery was significantly lower with combination therapy than tamsulosin monotherapy at 4 years.

doi:10.1016/j.jomh.2009.08.162