LONG TERM RESULTS OF AMITRIPTYLINE TREATMENT FOR INTERSTITIAL CYSTITIS

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INTRODUCTION AND OBJECTIVE: We recently reported a randomized controlled trial showing the significant improvement of interstitial cystitis (IC) symptoms under amitriptyline (AMI) treatment [van Ophoven et al., J. Urol. 172, 533]. We now present the long term results of a prospective observational study on the safety and efficacy of AMI for IC.
METHODS: The study enrolled 94 IC patients (82 women, 12 men) between October 2001 and September 2004 of whom 59 (63%) met the symptom criteria of the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK) for IC. The drug was taken strictly at bedtime following an established self-titration protocol without a limitation of the maximum daily dosage. Patients reporting improvement of symptoms on a 7-point centered scale were defined as treatment responders.
RESULTS: The mean follow up was 19 months and the mean treatment duration was 16 months. Response to treatment was observed in 60 patients (64%). Overall mean dosage was 55mg (range 12.5 - 150mg). Anticholinergic side effects occurred in 79 patients (84%) (dry mouth: 79%, weight gain: 59%). Patient overall satisfaction with the therapeutic result was either excellent or good in 47 patients (50%) (excellent satisfaction: 15%, good: 35%). Fair satisfaction due to minor response correlated with or without side effects was reported by 13 patients (14%). The drop-out rate was 27% (25 patients) after a mean treatment period of 6 weeks at a mean dosage of 70mg. Non-response to treatment was the primary reason for drop-out in all cases, side effects contributed to drop-out in 22 patients (88% of all drop-outs). The following symptoms improved statistically significant compared with baseline: Pain intensity (-22.1mm. on visual analogue scale, p=0.002), urgency (-19.7mm., p=0.004), 24-hr frequency (-6.9 voids/d, p=0.021), functional bladder volume (+32.9ml, p=0.039). The O´Leary/Sant score dropped by 7.9 points under treatment (p=0.004). Response rates and extent of symptom improvement did not differ significantly between the patients fulfilling NIDDK criteria and those with the “clinical diagnosis” of IC. Response to the drug was independent of IC subtype (classic vs. non-ulcerative type).
CONCLUSIONS: Long term AMI therapy is feasible, safe and effective for treating IC. Anticholinergic side effects are a key co-factor for treatment termination and constitute the major drawback of AMI treatment.

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