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Title: CLINICAL EFFICACY OF NAFTOPIDIL FOR BENIGN PROSTATIC HYPERPLASIA - USEFULNESS OF NAFTOPIDIL IN NON-RESPONDERS TO TAMSULOSIN HYDROCHLORIDE -

Aims of study:

The objective of this study was to investigate the clinical usefulness of naftopidil in patients whose chief complaints was nocturia with a nighttime urinary frequency of not less than three, as well as various filling and voiding symptoms, all of which were associated with benign prostatic hyperplasia.

Methods:

The study population comprises 17 patients who were afflicted with benign prostatic hyperplasia (BPH) with no urinary retention and whose urinary disorders and nighttime urinary frequency of not less than three were not mitigated after not less than six weeks of treatment with tamsulosin hydrochloride (0.2 mg after dinner). They were aged between 63 and 82 (mean: 74.0) years. On the basis of transrectal ultrasonography findings, the volume of the prostate was estimated at between 20.2 and 47.4 (mean: 22.1) ml. The subjects were treated with naftopidil at a daily dose of 75 mg after dinner, for six weeks as a rule. The following variables were determined before treatment initiation and after 6-week treatment, and compared:

1) subjective symptoms (daytime and nighttime urinary frequency, the International Prostate Symptom Score (IPSS) [filling and voiding symptoms], and Quality of Life assessment score (QOL score)); and

2) objective symptoms (uroflowmetry [voided volume, voiding time, maximum flow rate, and mean flow rate], and cystometry [first desire to void, maximum bladder capacity, maximum intravesical pressure, maximum detrusor pressure, and bladder compliance], and postvoid residual urine volume and rate). The efficacy of the drug was evaluated according to the urinary disturbance clinical study guideline of the Japanese Urological Association. In addition to global therapeutic efficacy, the usefulness of the drug was also assessed, in consideration of safety.

Results:

Among the 17 subjects, the treatment was discontinued in one subject due to mild nausea after treatment initiation, and in another subject due to increased daytime urinary frequency. Therefore, the remaining 15 subjects were included for therapeutic efficacy analysis. In the 15 subjects, significant improvement was noted in daytime and nighttime urinary frequency, IPSS, QOL score, maximum flow rate, mean flow rate, and bladder compliance. No significant difference was noted between the other variances obtained before and after treatment. Among the IPSS items, marked improvement was noted in nighttime urinary frequency and feeling of residual urine. Bladder instability, noted in five subjects before treatment initiation, completely

disappeared in all of the subjects after the 6-week treatment.

Daytime urinary frequency was improved from 7.7±1.9 (5 to 11) times before treatment initiation to 6.9±1.4 (4 to 8) after 6-week treatment; nighttime urinary frequency, 3.2±0.6 (3 to 5) to 1.0±0.8 (0 to 2); IPSS, 13.8±5.1 (7 to 22) to 4.6±2.9 (0 to 9); QOL score, 4.3±0.8 (3 to 6) to 1.3±0.8 (0 to 3); maximum flow rate, 9.8±4.1 (4.0 to 17.0) to 12.6±6.3 (7.0 to 27.0) ml/sec; mean flow rate, 4.4±1.5 (1.0 to 6.7) to 5.7±2.4 (3.0 to 10.0) ml/sec; bladder compliance, 16.7±12.9 (2.0 to 40.0) to 29.0±17.9 (5.4 to 67.0) ml/cmH_2O. For the global therapeutic efficacy, rating “markedly effective” was obtained in four subjects; “effective,” four subjects; “slightly effective,” seven subjects; and “impossible to evaluate,” two subjects (efficacy rate was 53.3%). No significant change was noted in laboratory measurements, blood pressure or pulse rate throughout the therapeutic course of any subject.

Regarding the usefulness, “ useful ” or higher rating was obtained in ten subjects (66.7%).

Conclusions:

Naftopidil was considered to be very effective in benign prostatic hyperplasia patients with various filling and voiding symptoms, particularly those whose chief complaint was nighttime urinary frequency of not less than three times or feeling of residual urine, and those complicated with bladder instability, as well as non-responders to treatment with tamsulosin hydrochloride.