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Original Article

Comparison of prazosin, terazosin and tamsulosin in the treatment of symptomatic benign prostatic hyperplasia: A short-term open, randomized multicenter study

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Abstract

Background: The objective of this open randomized clinical study was to compare the short-term efficacy and safety of three alpha-1 blockers, prazosin, terazosin and tamsulosin, in the treatment of lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH).

Methods: The study comprised 121 patients with symptomatic BPH who were randomized to receive 0.5 mg of prazosin twice daily, 0.5 mg of terazosin twice daily or 0.1 mg of tamsulosin once daily for the initial 2 weeks. The doses were doubled for the next 2 weeks. The primary variables assessed were a symptom score, changes in maximum and average urinary flow rate (Q_{max} and Q_{ave}), postvoid resisual urine volume and blood pressure.

Results: The percentage changes in the total symptom score from baseline were 38, 39 and 26% at 4 weeks by prazosin, terazosin and tamsulosin, respectively. Terazosin produced significantly higher improvement in four out of nine individual symptoms than tamsulosin ($P < 0.05$). A significant increase in Q_{max} or Q_{ave} in uroflowmetry was obtained in the prazosin and tamsulosin groups. Blood pressure remained unchanged in normotensive patients, but significantly decreased in hypertensive patients except for the tamsulosin group. Adverse events were minimal in all treatment groups.

Conclusions: The efficacy and safety profiles were different among the alpha-1 blockers at standard doses. Tamsulosin appears to be safer than the others for aged patients or patients with hypertension who have impaired blood pressure regulation, while terazosin is significantly effective in improving symptomatic score when compared with the others examined. It is recommended that the alpha-1 blocking agent and its optimal dose are selected on the basis of the baseline characteristics of the patients with symptomatic BPH.

Key words alpha-adrenergic blockade, symptomatic BPH.

Introduction

Symptomatic benign prostatic hyperplasia (BPH) is common among elderly men. Surgical treatment is not indicated for all of them and medical treatment with alpha-1 blockers or anti-androgens is a therapeutic alternative. Since prazosin was first introduced and was proved to be effective in improving symptoms caused by BPH,[1] a number of alpha-1 blockers have been explored for the medical treatment of BPH. The alpha-1 blockers which have been approved in Japan for clinical use for the treatment of BPH are prazosin,[2] tamsulosin,[3] terazosin,[4] urapidil,[5] and naftopidil.[6] Presently, however, very little information is available on the differences between these alpha-1 blockers in their efficacy and safety profiles in the treatment of BPH. Therefore, a short-term multicenter open study was designed. Patients with BPH were randomly assigned to receive prazosin, terazosin or tamsulosin and their clinical efficacy and safety were compared.

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Methods

Patients

The study protocol was authorized by the ethical committees of the cooperating hospitals (see Appendix for the list of the cooperating hospitals). Informed consent was obtained in advance from the patients participating in the study. Patients having mild to moderate benign prostatic hyperplasia with lower urinary tract symptoms (LUTS) and judged by the physicians not to have an indication for prostatectomy based on their clinical findings, were selected from outpatient clinic populations. Benign prostatic hyperplasia was diagnosed from the history, symptoms and physical examination. Excluded were patients with BPH who underwent prior prostatectomy, thermotherapy, anti-androgen therapy and catheterization because of urinary retention, those with other lower urinary tract disorders including prostatic cancer, neurogenic bladder, bladder stone and lower urinary tract infection, or those having cardiac, renal or hepatic insufficiency or dementia. Patients were not permitted to take concomitant drugs which could influence the outcome of the study, such as alpha- and beta-adrenoceptor agonists and antagonists, anticholinergics, antiandrogens and steroid 5-alpha-reductase inhibitor.

Study Design

In total, 121 patients were enrolled. After baseline evaluation for 1 week, the patients were randomly assigned to receive prazosin, terazosin or tamsulosin for 4 weeks according to their birth month. Initially, 0.5 mg of prazosin or terazosin twice daily, or 0.1 mg of tamsulosin once daily, was orally administered for 2 weeks to avoid the possibility of initial dose hypotension. The doses were doubled for the subsequent 2 weeks. A number of the patients were treated with 0.2 mg of tamsulosin throughout the treatment period because 0.1 mg capsules of tamsulosin were not available in some institutions participating in the study.

Assessment

The patients were asked to record the following items for three days before each visit throughout the study. Recorded items included nocturia, frequency, urgency, straining, decreased force and size of the urinary stream, intermittency and sensation of residual urine. These symptoms were rated on a 6-point scale from 0 (absence of symptoms) to 5 (severe symptoms) based on the international prostatic symptom score (IPSS).[7] As a modification we added prolonged micturition and hesitancy to the IPSS's seven items; these were rated 0–5 in the same manner. The daily records of these subjective impressions were reviewed by the urologists at each visit. Patients were asked to submit the records upon completion of the study. Mean of scores for 3 days in each item was calculated for the data analysis.

Urodynamic studies included the maximum and average urinary flow rates and voided/residual urine ratio. Residual urine volume was determined with either catheter insertion or a transabdominal ultrasonography. The measurement of these urodynamic parameters was considered to be valid only if the voided urine volume was more than 100 mL. Measurement of blood pressures and laboratory examinations, including blood chemistry studies and complete blood count, were done before and a day after the treatment. Adverse effects were carefully observed throughout the study and the urologists decided to continue or discontinue the treatment upon an occurrence of adverse events.

Data analysis and statistics

Data are expressed as mean ± standard deviation. For subjective scores intra- and inter-group differences were analyzed by the Wilcoxon signed rank test and the Kruskal–Wallis test, respectively. Intra- and inter-group differences of uroflowmetry parameters and blood pressures were tested by paired *t*-test and variance analysis, respectively. A P value less than 0.05 was considered to be significant.

Results

Of the 121 patients enrolled, 33, 42 and 46 were entered into the groups of prazosin, terazosin and tamsulosin, respectively. Sixteen patients (one in the prazosin, seven in the terazosin and eight in the tamsulosin group) were excluded from analysis, allowing evaluation of 105 patients (32, 35 and 38 in the prazosin, terazosin and tamsulosin group, respectively). The reasons for exclusion included failure to return for follow-up (two patients), concurrent illness (seven patients) and concomitant medication (seven patients). Of the 105 patients that qualified for evaluation, three patients (one in the prazosin and two in the terazosin group) discontinued the treatment because of adverse effects. The remaining 101 patients completed the 4-week treatment. Twenty-three patients out of the 38 evaluated from the tamsulosin group were given

0.2 mg tamsulosin throughout the treatment period for the reason described above.

There was no significant difference among treatment groups for bodyweight, height, the size of the prostate gland on a digital rectal examination and serum PSA level. The average age of patients was significantly ($P < 0.05$) higher in the tamsulosin group (mean 69.6) than in the prazosin group (mean 65.8) or terazosin group (mean 65.9). Baseline urodynamic parameters, which included Q_{max}, Q_{ave} and residual urine ratio, as well as baseline subjective symptom scores were similar among the treatment groups. In addition, there were no significant differences among the treatment groups in the mean baseline systolic or diastolic blood pressure, or pulse rate.

Symptom scores

Of 105 patients, 91 patients (27 in the prazosin, 31 in the terazosin and 33 in the tamsulosin group) completed symptom score questionnaires. The mean baseline scores and the mean changes at the end of the treatment period are summarized in Table 1 (2 weeks of data not shown). Percent improvement in total symptom score to the baseline was 22, 28 and 16% at 2 weeks and 38, 39 and 26% at 4 weeks in the prazosin, terazosin and tamsulosin group, respectively. The improvement at both 2 and 4 weeks was significant compared with the baseline in each group. The improvement at 4 weeks was also significantly greater than that at 2 weeks in each group ($P < 0.0001$ for prazosin and terazosin, $P < 0.01$ for tamsulosin). Terazosin revealed a significantly greater improvement in urgency, sense of residual urine, prolonged micturition and intermittency than tamsulosin ($P < 0.05$).

Overall efficacy on subjective symptom scores was also analyzed according to the Criteria for Treatment Efficacy in BPH, in which efficacy is categorized into four groups based on the ratio of post-treatment score to pretreatment score.[8] Ratios less than 25, 50 and 75% and more than 75% are categorized as excellent, good, fair and poor/worse, respectively. Excellent or good results in total symptom scores were attained in 40.7% of the prazosin, 32.3% of the terazosin and 18.2% of the tamsulosin group. As shown in Fig. 1, more patients who were treated with terazosin achieved excellent or good results in the irritative scores than in the obstructive scores. In contrast, in the prazosin group

Table 1 Effect of three alpha-1 blockers on subjective symptom scores

Item of symptom score		Prazosin ($n = 27$)	Terazosin ($n = 31$)	Tamsulosin ($n = 33$)	P value (between groups)
Irritative symptoms					
Nocturia	Baseline	1.86 ± 1.34	2.34 ± 1.71	2.52 ± 2.04	0.4694
	Change	−0.22 ± 0.71	−0.63 ± 1.26*	−0.50 ± 0.99*	0.4741
Frequency	Baseline	2.39 ± 1.40	2.74 ± 1.38	2.48 ± 1.67	0.7406
	Change	−0.71 ± 1.49*	−1.04 ± 1.06*	−0.57 ± 1.16*	0.1191
Urgency	Baseline	1.59 ± 1.53	2.74 ± 1.38	1.57 ± 1.47	0.4037
	Change	−0.96 ± 1.53*	−1.04 ± 1.06*	−0.02 ± 1.09	0.0315†
Sense of residual urine	Baseline	1.86 ± 1.31	2.20 ± 1.35	1.54 ± 1.39	0.0734
	Change	−0.79 ± 1.24*	−1.07 ± 1.19*	−0.37 ± 0.70	0.0493†
Obstructive symptoms					
Hesitancy	Baseline	1.80 ± 0.94	1.78 ± 1.08	1.33 ± 1.03	0.0937
	Change	−0.73 ± 0.86*	−0.82 ± 1.09*	−0.50 ± 0.74*	0.4095
Straining	Baseline	1.15 ± 1.12	1.32 ± 0.91	1.03 ± 0.99	0.3799
	Change	−0.56 ± 1.11*	−0.66 ± 0.91*	−0.33 ± 0.57*	0.2317
Prolonged micturition	Baseline	2.09 ± 1.03	2.32 ± 1.14	1.66 ± 1.00	0.0728
	Change	−0.86 ± 1.01*	−1.06 ± 1.00*	−0.56 ± 0.88*	0.0406†
Micturition force	Baseline	2.47 ± 0.89	2.42 ± 0.83	2.26 ± 0.92	0.7632
	Change	−0.81 ± 1.06*	−0.85 ± 0.67*	−0.68 ± 0.95*	0.502
Intermittency	Baseline	1.84 ± 1.31	2.20 ± 1.35	1.54 ± 1.39	0.0734
	Change	−0.79 ± 1.24*	−1.07 ± 1.19*	−0.37 ± 0.70*	0.0493†
Total of nine items	Baseline	17.04 ± 7.35	18.90 ± 8.02	15.63 ± 6.05	0.2603
	Change	−6.43 ± 7.81*	−7.44 ± 6.60*	−4.05 ± 4.54*	0.0759

Results are expressed as the mean ± SD. * Significantly different *vs* baseline ($P < 0.05$; Wilcoxon signed rank test); †significant difference between tamsulosin and terazosin ($P < 0.05$; Kruskal–Wallis test).

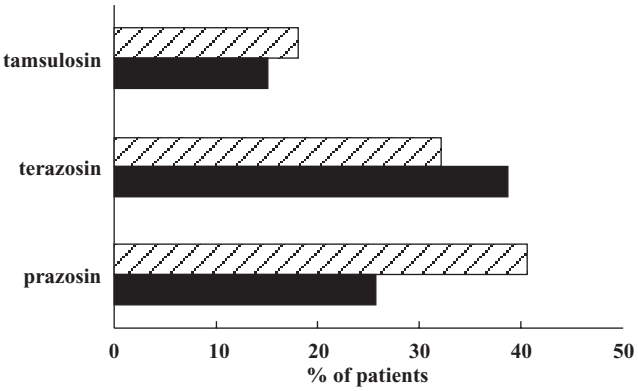

Fig. 1 Comparison of the percentage of the patients obtaining excellent or good improvement in irritative and obstructive symptom scores at 4 weeks after starting treatment with prazosin, terazosin and tamsulosin. Terazosin produced more excellent or good results in the irritative scores than in the obstructive scores. Prazosin produced more excellent or good results in the obstructive scores than in the irritative scores. ■, Irritative symptoms; ▨, obstructive symptoms.

more patients obtained excellent or good results in the obstructive scores than in the irritative scores.

Urodynamics

Valid uroflowetry results were obtained from 50 patients, 15 in the prazosin group, 17 in the terazosin group and 18 in the tamsulosin group. Patients' characteristics, including age, prostate size, alpha-1 blocker assigned and baseline total symptom score, were similar between patients with and without uroflowmetry data. Changes in the uroflowmetry parameters during treatment with alpha-1 blockers are given in Table 2. No significant improvement in uroflowmetry parameters was observed at 2 weeks (data not shown). A significant increase was observed in Q_{max} in the prazosin group and in Q_{ave} in the tamsulosin group at 4 weeks. No significant changes in residual urine ratio were observed in any treatment group.

Blood pressure

Blood pressure data were obtained from 50 patients, 18 in the prazosin group, 18 in the terazosin group and 14 in the tamsulosin group. There was no significant

Table 2 Effects of three alpha-1 blockers on uroflowmetry parameters and blood pressure

	Prazosin	Terazosin	Tamsulosin
Uroflowmetry	$n=15$	$n=17$	$n=18$
Maximum flow rate (mL/s)			
Baseline	10.4 ± 4.5	14.9 ± 6.0	12.5 ± 3.7
Change	2.8 ± 3.9*	1.2 ± 6.3	1.9 ± 4.3
Average flow rate (mL/s)			
Baseline	5.7 ± 3.2	6.8 ± 2.0	5.7 ± 1.7
Change	1.2 ± 2.4	1.0 ± 3.8	1.3 ± 2.3*
Residual urine (% of the voided)			
Baseline	24.7 ± 22.3	14.8 ± 15.7	10.2 ± 9.4
Change	− 8.2 ± 16.4	− 5.4 ± 11.4	− 1.0 ± 8.7
Blood pressure			
Normotensive	$n=10$	$n=10$	$n=5$
Systolic pressure (mmHg)			
Baseline	125 ± 8.1	122 ± 9.3	128 ± 2.2
Change	− 2.9 ± 13	0.2 ± 18	14 ± 16
Diastolic pressure (mmHg)			
Baseline	77 ± 9.4	78 ± 8	74 ± 4.6
Change	− 3.3 ± 8.8	− 5.1 ± 12	2.4 ± 14
Hypertensive†	$n=8$	$n=8$	$n=9$
Systolic pressure (mmHg)			
Baseline	149 ± 17	154 ± 16	153 ± 17
Change	− 5.3 ± 11	− 14 ± 7.7*	− 5 ± 14
Diastolic pressure (mmHg)			
Baseline	90 ± 8.6	89 ± 6.9	90 ± 7
Change	− 4.6 ± 3*	− 8.3 ± 7.7*	− 5.5 ± 7.6*

Results are expressed as the mean ± SD. * $P < 0.05$ *vs* baseline. † A hypertensive patient was defined as one who had a systolic pressure higher than 140 mmHg and/or a diastolic pressure higher than 90 mmHg during the baseline evaluation period.

difference in clinical background, including age, prostate size, alpha-1 blocker assigned and baseline total symptom score, between patients with and without blood pressure measurements. Mean changes in blood pressure from the baseline to the endpoint are summarized in Table 2. In hypertensive patients, no significant changes in blood pressure were observed at 2 weeks in any treatment groups (data not shown). Significant decreases in blood pressure were observed at 4 weeks in the prazosin and terazosin groups. In normotensive patients, no significant changes in systolic or diastolic blood pressure were observed in any treatment groups both at 2 and at 4 weeks.

Adverse events

A total of six adverse events were reported in five patients. All the adverse events occurred during the initial 2 weeks. One patient (3.1%) in the prazosin group had dizziness and discontinued the treatment. In the terazosin group three patients (8.5%) reported adverse events, one thirsty, one asthesia and one dizziness and nausea. They also discontinued the treatment. One patient (2.6%) in the tamsulosin group had fever, which was not likely to be treatment-related.

Discussion

The availability of several alpha-1 blockers with different pharmacological characteristics provides us with the opportunity to tailor the medical treatment of patients with BPH based upon their baseline characteristics, for example, severity and type of symptoms, concomitant cardiovascular diseases and other complications. However, to date, very little information is available on differences between alpha-1 blockers in their clinical efficacy and safety profiles. To our knowledge, the present study is the first randomized study that compares the efficacy and safety of more than two alpha-1 blockers in patients with symptomatic BPH.

In the present study, prazosin, terazosin and tamsulosin significantly improved the total symptom score. The efficacy of prazosin and terazosin were comparable to those in other studies[9,10] in which patients were treated with similar or larger doses of prazosin (4 mg/day) or terazosin (2–10 mg/day). Tamsulosin was less effective in decreasing symptom score than terazosin. A similar modest effect of tamsulosin on subjective symptoms was reported in one previous study[11] in which 0.2 mg of tamsulosin for 4 weeks produced only a 20% decrease of the total symptom score. In another randomized study with terazosin and tamsulosin,[12] a 36% decrease in total symptom score was reported with tamsulosin 0.2 mg daily for 8 weeks. In the previous studies in which 0.4 mg or more daily doses of tamsulosin were given, an improvement in symptom score by 35–48% was consistently reported. The results of this and other studies seem to indicate that the optimal dose of tamsulosin for the treatment of symptomatic BPH is 0.4 mg daily or more. For prazosin and terazosin, a daily dose of 2 mg seems to be reasonable for Japanese patients because subjective symptoms improved at a greater rate after the dose escalation from 1 mg to 2 mg with no further adverse events.

In the present study, terazosin appeared to be more effective in the improvement of irritative symptoms than prazosin and tamsulosin. Mechanisms of alpha-1 blockers to improve irritative symptoms in BPH are unclear. The irritative symptoms in patients with BPH are considered to be related to obstruction-induced changes in bladder function that lead to detrusor instability or decreased compliance. Therefore a direct effect of alpha-1 blockers on the bladder to increase the bladder capacity and to abolish detrusor instability[13] may contribute to relief of the irritative symptoms. The differences in efficacy profile of alpha-1 blockers observed in the present study may indicate differences in relative potencies of the alpha-1 blockers to the bladder outlet and the bladder itself.

In the present study, prazosin and terazosin significantly lowered the blood pressure in hypertensive patients, but not in normotensive patients. In contrast, tamsulosin did not affect the blood pressure in either normotensive or hypertensive patients. Recent cloning and pharmacological studies in human tissues have revealed the existence of at least three subtypes of the alpha-1 adrenoceptors: alpha-1A, -1B and -1D for native subtypes and alpha-1a, -1b and -1d for cloned counterparts.[14] It has been shown that the alpha-1A adrenoceptor subtype is primarily present and responsible for the contraction of smooth muscle of the prostate.[15] In vascular tissue, alpha-1A, -1B, and -1D adrenoceptors all seem to subserve the contractile response albeit to varying extents. Prazosin and terazosin are non-selective alpha-1 blockers with similar affinity to alpha-1A, -1B and -1D subtypes. Tamsulosin, however, is a selective alpha-1 blocker with a moderately higher affinity to alpha-1A subtype over alpha-1B and -1D subtype of adrenoceptors. Therefore, tamsulosin can be combined with cardiovascular drugs frequently prescribed in the BPH population for concomitant cardiovascular diseases such as hypertension, angina pectoris and heart failure without dose adjustment. It has been advocated that non-selective alpha-1 blockers, such as prazosin and terazosin,

which lower blood pressure, may have potential usefulness for monotherapy for patients with concomitant BPH and hypertension.[16] However, it should be noted that alpha-adrenergic blockade inherently carries the risk of impaired blood pressure control and homeostasis under stress, for example postural challenge, in both the normotensives and the hypertensives. Careful dose titration is necessary in patients treated with non-selective alpha-1 blockers for BPH or for BPH and hypertension. It was recently reported using the orthostatic stress test that more normotensive elderly men were found to be symptomatic hypotensives with terazosin than with tamsulosin.[17] Thus tamsulosin seems to be *a* safer alpha-1 blocker especially in elderly patients who have reduced vascular compliance and are prone to cardiovascular adverse effects of alpha-adrenergic blockade.

In the present study, terazosin and tamsulosin did not produce a significant increase in Q_{max} after the 4-week treatment period. As it has previously been shown that the improvements in urinary flow rates usually reach a plateau after 4–8 weeks of treatment with alpha-1 blockers, a longer treatment period may be needed to confirm our findings.

In summary, prazosin, terazosin and tamsulosin were well tolerated and significantly improved LUTS in patients with symptomatic BPH. But efficacy and safety profiles differ among the three alpha-1 blockers, at least in short-term treatment. Terazosin improved subjective symptoms more effectively than the others. Tamsulosin, however, did not change blood pressure in not only normotensive, but also hypertensive patients and was relatively free from the adverse effects often observed with non-selective alpha-1 blockers, such as dizziness and orthostatic hypotension. These differences may provide a clue to selecting the most suitable alpha-1 blocking agent and its optimal dose for the treatment of symptomatic BPH based on the baseline characteristics of each patient. Obviously further study in a double-blind setting with a longer treatment period is needed to fully characterize the differences in alpha-1 blockers clinically used in the treatment of symptomatic BPH.

Appendix I

Members of the BPH Medical Therapy Study Group

The members of the BPH Medical Therapy Study Group are: H Oshima, T Morita, T Tsujii, K Ishizaka, Tokyo Medical and Dental University School of Medicine; H Saito, T Yamada, Y Kamata, Kawagoe Medical Center, Saitama Medical College; K-I Yoshida, S Kitahara, M Honda, Dokkyo University School of Medicine; H Sekine, Mizonokuchi Hospital, Teikyo University School of Medicine; F Owada, A Noro, Omiya Red Cross Hospital; I Fukui, J Yonese, Cancer Institute Hospital; M Washizuka, Sasa Hospital; K Takagi, G Arai, Tokyo Metropolitan Tama Geriatric Hospital; M Ando, East Tokyo Metropolitan Hospital; K Hosoda, Tokyo Metropolitan Ootsuka Hospital; K Tari, Y Higashi, Saitama Cancer Center; D Ishiwata, T Toma, Showa Hospital.

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