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Comparison of Alfuzosin and Tamsulosin Once Daily for Treatment of Lower Urinary Tract Symptoms due to Benign Prostatic Hyperplasia: A Randomized, Prospective Study

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ABSTRACT

INTRODUCTION: The purpose of the study was to evaluate the efficacy and safety of a once-daily dose of alfuzosin (10 mg) and tamsulosin (0.4 mg) in men from India with lower urinary tract symptoms (LUTS) due to benign prostate hyperplasia (BPH).

METHODS: In this prospective study, 100 patients with LUTS due to BPH attending general surgery and urology departments were evaluated between October 2008 and November 2009. Patients were randomly assigned to a group taking alfuzosin 10 mg or a group taking tamsulosin 0.4 mg once daily, both without dose titration. The outcome measures were uroflowmetry results (Qmax, average flow rate, total flow time, and maximum flow time), ultrasonography results (PVR volume and prostate size), Quality of Life (QOL) scores, and International Prostate Symptom Scores (IPSS). Adverse events were recorded. Data were analyzed using *t* and Fisher exact tests.

RESULTS: Both alfuzosin and tamsulosin improved LUTS. All comparisons of every outcome measure (baseline to 1 month, baseline to 3 months, and 1 month to 3 months) showed statistically significant, progressive change for both patient groups. There were no significant group differences for any outcome measure. Both alfuzosin and tamsulosin were well tolerated, with similar reports of dizziness (6%), headache (4%), and asthenia (4%). The only significant group difference was for abnormal ejaculation, which was only reported by 2 of the 50 patients (4%) taking tamsulosin.

CONCLUSION: Treatment with both alfuzosin and tamsulosin significantly improved all measures of uroflowmetry, ultrasonography, and quality of life. Both medications were well tolerated, but ejaculatory abnormalities were observed only in patients taking tamsulosin.

Abbreviations and Acronyms

BPH = benign prostatic hyperplasia;
IPSS = International Prostate Symptom Score
LUTS = lower urinary tract symptoms
PVR = postvoid residual
Qmax = maximum flow rate
QOL = quality of life

KEYWORDS: Alpha blocker; Alfuzosin; Tamsulosin; LUTS; BPH

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original study

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INTRODUCTION

Lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia (BPH) are very common in aging men. LUTS are due to static (ie, fixed, structural) components related to the bulk of the enlarged prostate impinging on the urethra, and to dynamic (ie, physiologic, reversible) components related to the tension of the prostatic smooth muscle in the prostate, prostate capsule, and bladder neck [1]. The increase in smooth muscle tone in the prostate and prostatic urethra is mediated by stimulation of α_1 adrenergic receptors in the lower urinary tract (eg, bladder neck, urethra, prostate capsule, stroma).

Alpha-1 adrenoceptor antagonists are considered the first line of treatment for managing LUTS associated with BPH [2]. Alpha$_{1A}$ receptors predominate in the bladder base, prostate, and ureterotrigonal area including the distal 5 cm of the ureter. They are also present in blood vessels.

Alpha-1 adrenoceptor antagonists such as prazosin, tarazosin, and doxazosin have side effects such as dizziness, asthenia, postural hypotension, and syncope. Alfuzosin and tamsulosin appear to be better tolerated and have higher uroselectivity.

Tamsulosin is the first selective α_1 adrenoceptor antagonist that is more selective for α_{1A} and, to a lesser extent, α_{1D} than the α_{1B} adrenoceptor [3]. The tamsulosin α_{1A}:α_{1B} affinity is 38:1. Tamsulosin has approximately 12 times the affinity for α_1 adrenoceptor in the human prostate than in blood vessels. Dizziness, retrograde ejaculation, rhinitis, and fatigue have been reported with tamsulosin [4-6].

Alfuzosin differs from other quinazoline derivatives (eg, prazosin, terazosin, doxazosin) by the absence of piperidine moiety and the presence of a diaminopropyl spacer, which confers alfuzosin with special biochemical properties. Alfuzosin is a uroselective α_1-adrenergic antagonist that is distributed preferentially in the prostate. It decreases the sympathetically controlled tone of prostatic smooth muscle. It is highly soluble in water. Because of limited lipophilicity, it cannot easily penetrate the blood-brain barrier. Therefore, alfuzosin has a lower potential to cause dizziness, asthenia, or somnolence than other α_1-adrenergic antagonists [7-10].

Although there are previous reports comparing alfuzosin and tamsulosin in the literature, these reports have not included patients from India. The effects of the drugs on people from a different geographic region with different dietary and lifestyle influences are unknown. The purpose of the present prospective study was to evaluate the efficacy and safety of alfuzosin 10 mg once daily and tamsulosin 0.4 mg once daily without dose titration for 12 weeks in patients from India.

METHODS

This prospective study was conducted on 100 patients with LUTS due to BPH. The patients were evaluated in the General Surgery or Urology Outpatient Departments at Pt. B. D. Sharma Postgraduate Institute of Medical Sciences, Rohtak, India, between October 2008 and November 2009. The study protocol was approved by the ethics committee of the authors' institution. Written informed consent was obtained from all selected patients.

Patient Selection

The inclusion criteria of patients with LUTS due to BPH were: (1) age more than 45 years; (2) urine storage symptoms (eg, increase in daytime frequency, urgency, nocturia) and/or voiding symptoms (eg, difficulty initiating micturition, feeling of incomplete voiding, impaired quality of stream, interruption of stream) that were symptomatic of BPH for at least 6 months; (3) daytime frequency ≥ 8 or nocturnal micturitions ≥ 2; (4) maximum flow rate (Qmax) between 5 mL/s and 15 mL/s with a voided volume of at least 150 mL; (5) postvoid residual (PVR) urine < 150 mL, determined by abdominal ultrasound; (6) International Prostate Symptom Score (IPSS) ≥ 13 points; IPSS Bother score ≥ 3 points.

Exclusion criteria were: (1) previous prostate surgery, severe visceral disease, postural hypotension, neurogenic bladder dysfunction, suspected prostate cancer, urethral stricture disease, history of pelvic irradiation, bladder neck disease, acute bacterial prostatitis, acute urinary tract infection, or urolithiasis; (2) history of concomitant medication that may alter the voiding pattern before inclusion (eg, calcium antagonist, monoamine oxidase inhibitors, anticholinergic drugs) or antipsychotic medication; (3) active hematuria, renal insufficiency (serum creatinine ≥ 2.0 mg/dL), severe hepatic impairment (transminases ≥ 2 times the upper normal limit and/or total bilirubin ≥ 1.5 mg%); (4) insulin-dependent diabetes mellitus, severe heart disease (eg, myocardial infarction or cerebrovascular accident in the previous 6 months); (5) ascertained or suspected hypersensitivity to alfuzosin or tamsulosin.

Study Protocol

Every selected patient was assessed by clinical history, general physical examination, digital rectal examination, focal neurological examination, blood urea, serum creatinine, blood sugar, serum bilirubin, serum transaminases, serum electrolyte, complete urine examination, urine culture sensitivity, prostate-specific antigen, ultrasonograpy for prostate size, PVR volume, uroflowmetry, IPSS, and quality of life (QOL) score.

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A total of 100 patients met the inclusion criteria for the study. The patients were randomly assigned to one of 2 groups. Group 1 (n = 50) received tamsulosin 0.4 mg once daily; group 2 (n = 50) received alfuzosin 10 mg once daily. Both medications were taken for 3 months.

The mean (SD) patient age was 64.46 (9.27) years in the group taking tamsulosin and 64.30 (8.89) years in the group taking alfuzosin. There was no significant group difference in age (P = .93).

The selected patients were evaluated at baseline and 1 month and 3 months into the treatment protocol.

Data Analysis

The outcome measures were uroflowmetry results (Qmax, average flow rate, total flow time, and maximum flow time), ultrasonography results (PVR volume and prostate size), QOL scores, and IPSS. Adverse events that were observed or reported by the patients were recorded.

The *t* test was used to compare changes from baseline and differences between groups for continuous outcome measures. The Fisher exact test was used to compare changes from baseline and differences between groups for qualitative outcome measures. $P < .05$ was used to indicate statistical significance. A power analysis was not completed. Therefore, the possibility of a type II error exists for this sample.

RESULTS

Uroflowmetry Outcome Measures

Maximum flow rate (Qmax). Patients in both treatment groups experienced a significant improvement in Qmax. All comparisons of mean Qmax (baseline to 1 month, baseline to 3 months, and 1 month to 3 months) showed a significant, progressive increase for patients in both groups ($P < .05$). When compared with baseline, the final mean Qmax in the group taking alfuzosin increased 2.14 mL/s (23%); the mean Qmax in the group taking tamsulosin increased 2.05 mL/s (22%) (Table 1; Figure 1). There were no significant group differences in Qmax ($P > .05$).

Average flow rate. Patients in both treatment groups experienced a significant improvement in average flow rate. All mean comparisons of average flow rate (baseline to 1 month, baseline to 3 months, and 1 month to 3 months) showed a significant, progressive increase for patients in both groups ($P < .05$). When compared with baseline, the final means of average flow rate increased 1.78 mL/s (34%) and 1.79 mL/s (33%) for patients taking alfuzosin and tamsulosin, respectively (Table 1; Figure 2). There were no significant group differences in average flow rate ($P > .05$).

Total flow time. Patients in both treatment groups experienced a significant improvement in total flow time. All comparisons of mean total flow time (baseline to 1 month, baseline to 3 months, and 1 month to 3 months) showed a significant, progressive decrease for patients in both groups ($P < .05$). When compared

Table 1. Means and Standard Deviations (SD) for the Outcome Measures Used to Compare Patients Taking Alfuzosin and Tamsulosin at Baseline, 1 Month, and 3 Months of Treatment (N = 100).
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Outcome Measure	Alfuzosin (n = 50)						Tamsulosin (n = 50)					
	Baseline		1 Month		3 Months		Baseline		1 Month		3 Months	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Uroflowmetry Measures												
Qmax (mL/s)	9.34	1.31	11.27	0.87	11.48	0.83	9.44	1.06	11.01	0.85	11.49	0.8
Average flow rate (mL/s)	5.24	1.00	6.90	0.64	7.02	0.69	5.41	1.03	6.92	0.87	7.20	0.8
Total flow time (s)	39.10	6.30	31.91	3.56	31.10	2.99	39.38	7.95	31.25	4.19	30.12	4.08
Maximum flow time (s)	12.01	3.63	8.74	2.10	8.21	1.91	13.45	3.54	9.58	2.27	8.37	1.94
Ultrasonography Measures												
PVR volume (mL)	75.04	28.8	20.20	15.09	10.22	6.75	84.70	27.26	20.90	20.14	10.60	8.05
Prostate size (g)	57.76	7.32	58.12	7.68	58.24	7.67	61.72	7.52	62.18	7.58	63.34	7.53
Quality of Life (score)	5.22	4.78	3.2	3.42	2.78	2.97	5.24	0.71	3.22	0.81	2.82	0.59
IPSS (score)	22.24	0.54	14.82	0.69	13.46	0.50	21.08	3.54	13.6	2.76	12.6	2.25

Abbreviations: Qmax, maximum flow rate; PVR, postvoid residual; IPSS, International Prostate Symptom Score

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Figure 1. Mean Maximum Flow Rates in mL/s for Patients Taking Alfuzosin and Tamsulosin at Baseline, 1 Month, and 3 Months of Treatment.
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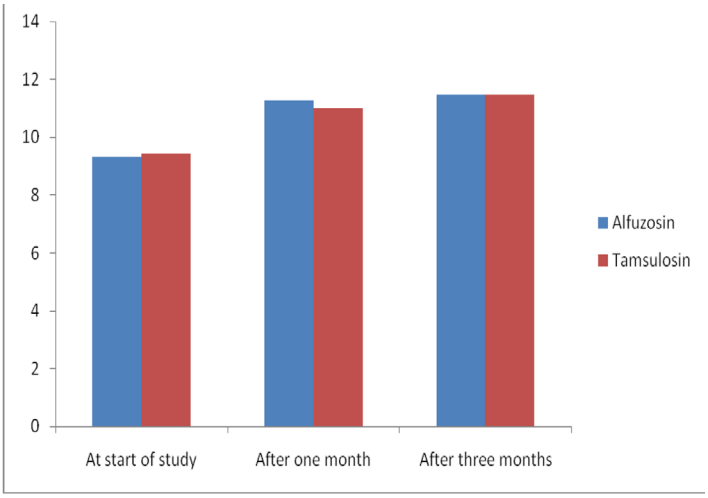

Figure 2. Means of Average Flow Rate in mL/s for Patients Taking Alfuzosin and Tamsulosin at Baseline, 1 Month, and 3 Months of Treatment.
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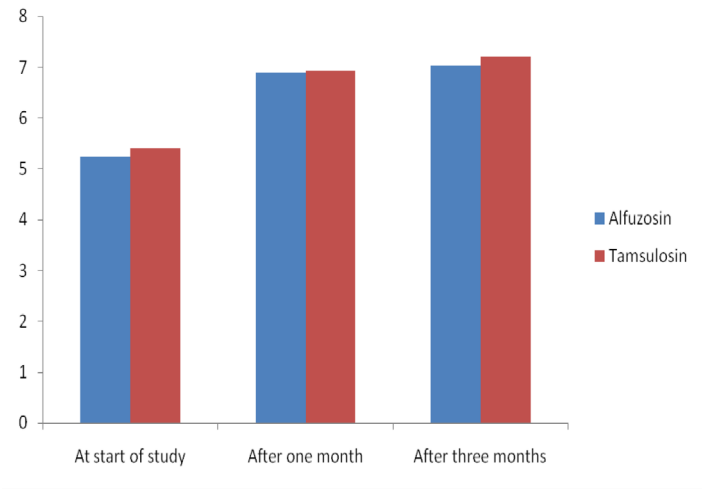

with baseline, the final means of total flow time decreased 8.0 seconds (20%) and 9.26 seconds (24%) from baseline for patients taking alfuzosin and tamsulosin, respectively (Table 1). There were no significant group differences in total flow time ($P > .05$).

Maximum flow time. Patients in both treatment groups experienced a significant improvement in maximum flow time. All comparisons of mean maximum flow time (baseline to 1 month, baseline to 3 months, and 1 month to 3 months) showed a significant, progressive decrease for patients in both groups ($P < .05$). When compared with baseline, the final means of maximum flow time decreased 3.8 seconds (32%) and 5.08 seconds (38%) for patients taking alfuzosin and tamsulosin, respectively (Table 1). There were no significant group differences in total flow time ($P > .05$).

Ultrasonography Outcome Measures

PVR volume. Patients in both treatment groups experienced a significant improvement in PVR volume. All comparisons of mean PVR volume (baseline to 1 month, baseline to 3 months, and 1 month to 3 months) showed a significant, progressive decrease for patients in both groups ($P < .05$). When compared with baseline, the final mean PVR volume decreased 64.82 mL (86%) and 74.1 mL (88%) for patients taking alfuzosin and tamsulosin, respectively (Table 1). There were no significant group differences in PVR volume ($P > .05$).

Prostate size. The mean prostate size did not show any statistically significant change across evaluation times or between groups ($P > .05$) (Table1).

Quality of Life Index and International Prostate Symptom Score

QOL index. Patients in both treatment groups demonstrated a similar progressive decrease in QOL scores. All comparisons of mean QOL (baseline to 1 month, baseline to 3 months, and 1 month to 3 months) were significantly different for patients in both groups ($P < .05$). When compared with baseline, the final mean QOL score for the group taking alfuzosin decreased 2.48 points (48%); the mean QOL score for the group taking tamsulosin decreased 2.42 points (46%). There were no significant group differences in QOL scores ($P > .05$).

IPSS. Patients in both treatment groups experienced a significant improvement in IPSS. All comparisons of mean IPSS (baseline to 1 month, baseline to 3 months, and 1 month to 3 months) showed a significant, progressive decrease in IPSS scores for patients in both groups ($P < .05$). When compared with baseline, the final mean IPSS for the group taking alfuzosin decreased 8.78 points (39%); the mean IPSS for the group taking tamsulosin decreased 8.48 points (40%) (Table 1; Figure 3). There were no significant group differences in IPSS ($P > .05$).

The mean scores for the efficacy variables in the IPSS questionnaire are contained in Table 2. When the means at baseline were compared with the means at the 3-month

Figure 3. Mean International Prostate Symptom Scores for Patients Taking Alfuzosin and Tamsulosin at Baseline, 1 Month, and 3 Months of Treatment.
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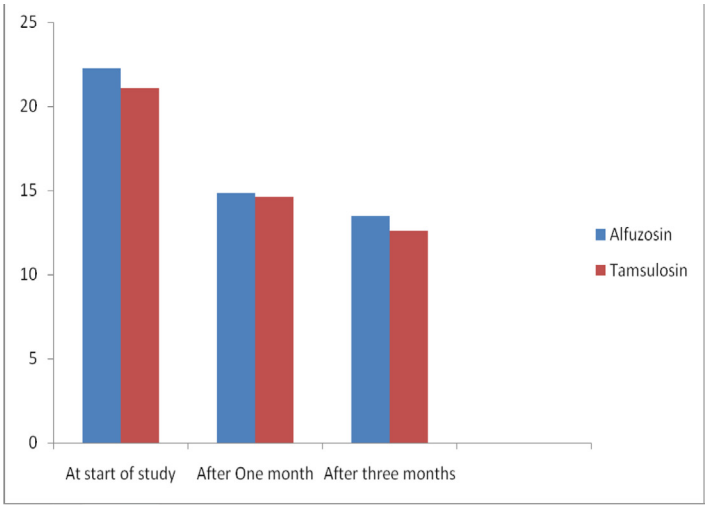

evaluation, every score decreased for patients in both groups.

Safety

Overall, treatment with alfuzosin 10 mg once daily and tamsulosin 0.4 mg once daily without dose titration was well tolerated. No patient discontinued the treatment due to adverse events in either group.

A total of 7 patients taking alfuzosin complained of tolerable dizziness (6%), headache (4%), and asthenia (4%). No other adverse symptoms were reported.

A total of 8 patients taking tamsulosin reported tolerable dizziness (4%), headache (4%), and asthenia (4%). A total of 3 patients (6%) reported ejaculation abnormalities; the most common was painful ejaculation in 4% of the patients. No other adverse symptoms were reported.

Abnormal ejaculation, reported by 6% of the patients taking tamsulosin, was not observed in the group taking alfuzosin; the group difference was statistically significant for this variable ($P < .05$).

DISCUSSION

Alpha adrenergic receptor blockers are considered the first line of treatment for LUTS that are suggestive of BPH, because they provide rapid and sustained relief regardless of prostate size. Alpha blocker therapy is based on the hypothesis that LUTS are caused by α_1 adrenergic-mediated contraction of smooth muscle cells within the prostate, prostate capsule, and bladder neck that results in benign prostatic obstruction (BPO). Alfuzosin, doxazosin, tamsulosin, and terazosin have been extensively studied in various randomized, controlled trials with duration of up to 12 months. A review of these studies by Chapple [11] showed that symptom scores improved by 4-6 points and Qmax by 2-3 mL/s, indicating effectiveness for all of the α_1 blockers.

Adrenergic receptors are involved in the regulation of cardiovascular, genitourinary, and central nervous system function. The second generation (eg, alfuzosin, doxazosin, terazosin) and third generation (eg, tamsulosin) α_1 blocker used for treatment of LUTS and BPH demonstrate greater selectivity for α_1 adrenergic receptors and α_2 adrenergic receptors. Unlike doxazosin and terazosin that were initially developed for

Table 2. Means and Standard Deviations (SD) for Variables on the International Prostate Symptom Index (IPSS) Used to Compare Patients Taking Alfuzosin and Tamsulosin at Baseline, 1 Month, and 3 Months of Treatment (N = 100).
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Outcome Measure	Alfuzosin (n = 50)						Tamsulosin (n = 50)					
	Baseline		1 Month		3 Months		Baseline		1 Month		3 Months	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Storage/irritative symptoms												
Frequency	4.46	0.61	3.26	0.69	3.12	0.91	4.34	0.47	3.44	0.78	3.04	0.75
Urgency	4.32	0.71	2.84	0.80	2.50	0.81	4.21	0.57	2.82	0.77	2.22	0.58
Nocturia	4.06	0.86	2.86	0.80	2.46	0.64	3.82	0.56	2.52	0.70	2.12	0.52
Voiding/obstructive symptoms												
Incomplete emptying	2.60	1.17	1.66	0.47	1.58	0.53	3.06	1.72	1.94	0.84	1.72	0.14
Intermittency	1.62	0.94	1.02	0.14	1.04	0.28	1.20	0.40	1.02	0.14	1.02	0.14
Poor flow	3.74	1.19	2.16	1.24	1.84	0.88	3.00	0.84	1.82	0.46	1.46	0.45
Hesitancy	1.64	0.96	1.02	0.14	1.04	0.28	1.44	0.81	1.04	0.19	1.02	0.14

the treatment of hypertension, alfuzosin and tamsulosin are considered clinically uroselective. This means that each agent affects the prostate gland to a greater extent than it affects the vascular system, thereby minimizing vasodilatory side effects [12,13].

The main side effects associated with α_1 blockers are orthostatic hypotension, dizziness, headache, asthenia, rhinitis, and ejaculation abnormalities. The uroselective α_1 receptors alfuzosin and tamsulosin have the least effect on the cardiovascular system. They require no dose titration and allow convenient once-daily dosing [7,10].

In a meta-analysis by Djavan et al [14], studies of all α_1 adrenoceptor antagonists showed an increase in urinary flow ranging between 15% and 30%. These changes were approximately 10% to 15% larger than what could be achieved by placebo treatment. Buzelin et al [15] reported a mean increase in Qmax of 16 mL/s (16%) for patients taking both alfuzosin (2.5 mg, 3 times daily) and tamsulosin (0.4 mg, once daily). In a study by Nordling [16], Qmax increased 15% for patients taking both alfuzosin (10 mg and 15mg, once daily) and tamsulosin (0.4 mg, once daily). In the present study, the mean Qmax for patients taking both tamsulosin and alfuzosin increased significantly from baseline by 22% and 23%, respectively. There were no significant group differences. Improvement in Qmax was comparable with that shown in the previous studies.

The meta-analysis by Djavan et al [14] also showed that all α_1 adrenoceptor antagonists resulted in a decrease in IPSS by approximately 30% to 45%. These changes were 10% to 20% larger than what was caused by placebo treatment. Buzelin et al [15] reported a mean decrease in the Boyarsky symptom score of 4.1 units (39.8%) and 3.8 units (38.8%) for patients taking alfuzosin (2.5 mg, 3 times daily) and tamsulosin (0.4 mg, once daily), respectively. In the present study, the mean IPSS for patients taking tamsulosin and alfuzsoin decreased significantly 8.48 units (40%) and 8.78 units (39%) from baseline. There were no significant group differences. These results are comparable with those found in the previous studies.

Comparative evaluation of alfuzosin and tamsulosin in the present and previous studies suggests that dizziness, headache, and asthenia are the most common adverse events for both medications [14-16]. Abnormal ejaculation, reported by 4% of the present patients taking tamsulosin, was the only symptom that was not observed in the group taking alfuzosin. There was a statistically significant group difference for this side effect ($P < .05$).

CONCLUSION

In patients with lower urinary tract symptoms due to benign prostate hyperplasia, both alfuzosin and tamsulosin were well tolerated and showed similar efficacy. Alfuzosin may be preferred for sexually active patients, due to fewer reported ejaculatory abnormalities. The patients from India responded to these drugs in a manner similar to that reported for patients from other geographic regions.

Conflict of Interest: none declared.

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