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Comparative Evaluation of the Effectiveness of Tamsulosin and Silodosin in Patients with Benign Prostatic Hyperplasia and Diabetes Mellitus

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Abstract: The aim of the study was to conduct a comparative evaluation of the clinical efficacy and safety of the α1-adrenergic blockers tamsulosin and silodosin in patients with benign prostatic hyperplasia (BPH) associated with type 2 diabetes mellitus. The study included 40 patients over 60 years of age. Urodynamic parameters, the severity of lower urinary tract symptoms (LUTS), IPSS score, the frequency of adverse effects, and the impact of the drugs on blood pressure were assessed.

Keywords: benign prostatic hyperplasia, diabetes mellitus, tamsulosin, silodosin, lower urinary tract symptoms, IPSS.

Introduction

Benign prostatic hyperplasia (BPH) is one of the most common urological diseases in elderly and senile men. According to epidemiological studies, clinical manifestations of BPH are detected in more than 50% of men over the age of 60, and the prevalence of the disease steadily increases with advancing age. The main clinical manifestation of BPH is lower urinary tract symptoms (LUTS), including obstructive and irritative disorders, which significantly impair patients' quality of life and lead to a decrease in social activity[1].

The problem of BPH is of particular clinical significance in patients with concomitant type 2 diabetes mellitus. Diabetes mellitus is widespread among the elderly population and is often combined with diseases of the genitourinary system. Diabetic autonomic neuropathy, microangiopathy, and metabolic disorders have a negative impact on lower urinary tract function, contributing to the development of detrusor hypoactivity, impaired bladder sensation, and aggravation of infravesical obstruction. As a result, in patients with a combination of BPH and diabetes mellitus, LUTS are usually more pronounced and have a more refractory course, respond less favorably to standard therapy, and are more often accompanied by increased post-void residual urine and nocturia[2-3].

According to current clinical guidelines of the European Association of Urology (EAU), α1-adrenergic blockers are first-line drugs for the treatment of moderate to severe LUTS caused by BPH. Their therapeutic effect is achieved through relaxation of the smooth muscle of the prostate, bladder neck, and prostatic urethra, leading to a reduction in the dynamic component of obstruction and improvement of urodynamic parameters. Among the most widely used agents in this group are tamsulosin and silodosin[6-7].

Tamsulosin is a selective α1A/α1D-adrenergic blocker and has been successfully used in clinical practice for many years. The drug is characterized by proven efficacy, good tolerability, and a relatively favorable safety profile. However, in elderly patients, especially those with concomitant cardiovascular disease and diabetes mellitus, tamsulosin therapy may be associated with undesirable hemodynamic effects, including decreases in blood pressure and dizziness[7-8].

Silodosin is a highly selective α1A-adrenergic blocker and is distinguished by minimal effects on vascular α1B-adrenergic receptors. Owing to this property, the drug provides a more pronounced effect on the obstructive component of LUTS with a lower risk of systemic vascular adverse effects. At the same time, the high selectivity of silodosin is associated with a higher incidence of ejaculatory disorders, particularly retrograde ejaculation, which may limit its use in some patients[9].

Despite the availability of numerous studies addressing the efficacy of α1-adrenergic blockers in BPH, data on the comparative efficacy and safety of tamsulosin and silodosin in patients with concomitant diabetes mellitus remain limited. Given the specific pathophysiological features of micturition disorders in diabetes, as well as the high risk of cardiovascular complications and polypharmacy in this patient population, the choice of the optimal α1-adrenergic blocker requires additional clinical justification.

In view of the above, a comparative analysis of the efficacy and tolerability of tamsulosin and silodosin in patients over 60 years of age with BPH and diabetes mellitus represents a relevant task in modern urology and has important practical significance for optimizing pharmacological therapy in this group of patients.

Aim of the Study

To conduct a comparative evaluation of the efficacy and safety of tamsulosin and silodosin in patients with benign prostatic hyperplasia (BPH) associated with type 2 diabetes mellitus.

Materials and Methods

The study included 40 patients diagnosed with BPH and concomitant type 2 diabetes mellitus. The mean age of the patients ranged from 65 to 78 years (all patients were over 60 years old). The patients were divided into two groups: **Group 1 (n = 20):** received tamsulosin at a dose of 0.4 mg once daily. **Group 2 (n = 20):** received silodosin at a dose of 8 mg once daily. The duration of follow-up was 12 weeks. The following parameters were evaluated: average urinary flow rate (Qave); maximum urinary flow rate (Qmax); post-void residual urine volume; severity of lower urinary tract symptoms (LUTS); total International Prostate Symptom Score (IPSS); frequency of nocturia; adverse effects, including retrograde ejaculation and decreased arterial blood pressure.Statistical analysis was performed using standard methods of variation statistics.

Results of the study:

As shown in Table 1, prior to therapy, the differences between the groups in maximum (Qmax) and average (Qave) urinary flow rates were not statistically significant, confirming the comparability of the study groups

Table 1. Urinary flow rate parameters before and after treatment

№	Parameter	Tamsulosin (n = 20)	Silodosin (n = 20)
1.	Qmax before treatment (mL/s)	9,1 ± 1,3	9,0 ± 1,2
2.	Qmax after treatment (mL/s)	13,8 ± 1,5	**15,2 ± 1,6**
3.	Qave before treatment (mL/s)	5,2 ± 0,9	5,1 ± 0,8
4.	Qave after treatment (mL/s)	8,0 ± 1,1	**9,1 ± 1,2**

($p<0.05$)

After the 12-week treatment course, both groups demonstrated a significant increase in Qmax and Qave compared to baseline values ($p<0.05$). Moreover, patients receiving silodosin showed a statistically significantly greater improvement in both maximum and average urinary flow rates compared to the tamsulosin group ($p<0.05$).

These results indicate a more pronounced improvement in urodynamic parameters with silodosin therapy.

Table 2. Dynamics of post-void residual urine and nocturia

№	Parameter	Tamsulosin (n = 20)	Silodosin (n = 20)
1.	Residual urine before treatment (mL)	82 ± 15	85 ± 17
2.	Residual urine after treatment (mL)	45 ± 12	**32 ± 10**
3.	Nocturia before treatment (episodes/night)	3,4 ± 0,6	3,5 ± 0,5
4.	Nocturia after treatment (episodes/night)	2,1 ± 0,4	**1,7 ± 0,3**

(p<0.05)

According to the data in Table 2, prior to treatment, post-void residual urine volume and the frequency of nocturia did not differ significantly between the two groups.

After the treatment course, a significant reduction in post-void residual urine was observed in both the tamsulosin and silodosin groups, reflecting improved bladder emptying.

However, the decrease in residual urine was more pronounced in the silodosin group, confirming its more effective impact on the dynamic component of obstruction. A similar trend was observed for nocturia: the frequency of nighttime urination decreased in both groups, but the reduction was more noticeable in patients receiving silodosin, which positively affects the quality of life in elderly patients.

Table 3. Assessment of LUTS severity and IPSS score

№	Parameter	Tamsulosin (n = 20)	Silodosin (n = 20)
1.	**IPSS before treatment (points)**	21,5 ± 2,1	22,0 ± 2,3
2.	**IPSS afetr treatment (points)**	14,2 ± 1,9	**11,8 ± 1,7**
3.	Severity of LUTS (reduction, %)	34%	**46%**

(p<0.05)

As shown in Table 3, the baseline severity of lower urinary tract symptoms (LUTS) and the total IPSS score in both groups corresponded to a severe degree of symptomatology and were comparable.
At the end of the treatment course, a significant reduction in IPSS scores was observed in both groups, indicating the high clinical efficacy of α1-adrenergic blockers.
However, patients receiving silodosin demonstrated a more pronounced decrease in both IPSS scores and LUTS severity compared to the tamsulosin group.
This finding indicates a stronger effect of silodosin on both obstructive and irritative symptoms, which is particularly important in patients with diabetes mellitus, who often have neurogenic disturbances of micturition.

Table 4. Therapy-related adverse effects

№	adverse effect	Tamsulosin (n, %)	Silodosin (n =, %)
1.	Retrograde ejaculation	2 (10%)	6 (30%)
2.	Decrease in blood pressure	4 (20%)	1 (5%)
3.	Dizziness	3 (15%)	2 (10%)

The analysis of adverse effects presented in Table 4 demonstrates differences in the safety profiles of the studied drugs. In the silodosin group, retrograde ejaculation was observed more frequently, which is associated with its high selectivity for α1A-adrenergic receptors and pronounced relaxation of the bladder neck.
At the same time, patients receiving tamsulosin more often experienced a decrease in blood pressure and episodes of dizziness, which may be explained by the lower selectivity of the drug and its effect on vascular α1B-adrenergic receptors.
These findings are of particular clinical importance in elderly patients with concomitant cardiovascular disease, in whom the risk of orthostatic hypotension necessitates a cautious choice of therapy.

Overall, the results of the study confirm that both drugs effectively improve urodynamic parameters and reduce the severity of lower urinary tract symptoms in patients with benign prostatic hyperplasia and diabetes mellitus. However, silodosin demonstrates a more pronounced clinical effect, whereas tamsulosin has a more favorable profile with regard to sexual adverse effects.

Discussion

The present study made it possible to conduct a comparative evaluation of the clinical efficacy and safety of the α1-adrenergic blockers tamsulosin and silodosin in patients with benign prostatic hyperplasia (BPH) associated with type 2 diabetes mellitus. This patient population is of particular clinical interest, since diabetic neuropathy and microangiopathy can aggravate infravesical obstruction and reduce the effectiveness of standard pharmacological therapy.

The results obtained demonstrated that both drugs provide a statistically significant improvement in urodynamic parameters, including increases in maximum and average urinary flow rates, as well as a reduction in post-void residual urine volume ($p<0.05$). These findings confirm the appropriateness of using α1-adrenergic blockers as first-line therapy in elderly patients with BPH and concomitant diabetes mellitus.

At the same time, comparative analysis revealed a more pronounced clinical effect of silodosin for most of the functional parameters studied. Patients receiving silodosin showed a statistically significantly greater increase in Qmax and Qave, as well as a more marked reduction in residual urine volume compared with the tamsulosin group ($p<0.05$). This is likely attributable to the high selectivity of silodosin for α1A-adrenergic receptors, which predominate in the tissues of the prostate, bladder neck, and prostatic urethra. As a result, a more effective reduction of the dynamic component of obstruction is achieved without significant systemic vascular effects.

The impact of therapy on the severity of lower urinary tract symptoms (LUTS) and quality of life is of particular importance in the studied patient population. During the study, a statistically significant decrease in the total IPSS score and LUTS severity was observed in both groups ($p<0.05$). However, patients treated with silodosin experienced a more pronounced regression of symptoms, indicating its advantage in the correction of both obstructive and irritative symptoms. This is especially relevant in patients with diabetes mellitus, who often exhibit impaired bladder sensation and detrusor contractility.

With regard to nocturia, positive changes were also observed in both groups; however, a more significant reduction in the frequency of nighttime voiding was noted with silodosin therapy ($p<0.05$). The reduction of nocturia is of substantial clinical importance, as this symptom markedly worsens sleep quality, overall well-being, and functional status in elderly patients.

Analysis of the safety profile revealed differences in the nature of adverse effects between the studied drugs. In the silodosin group, retrograde ejaculation was observed statistically significantly more often ($p<0.05$), which can be explained by pronounced relaxation of the bladder neck and internal sphincter. Although this adverse effect does not pose a threat to the patient's life, it may negatively affect treatment satisfaction and therefore requires prior patient counseling.

At the same time, patients receiving tamsulosin more frequently experienced decreases in blood pressure and episodes of dizziness ($p<0.05$), which is of particular relevance in elderly patients with concomitant cardiovascular disease. In the setting of diabetes mellitus, which is often accompanied by autonomic neuropathy, the risk of orthostatic hypotension necessitates a cautious approach to drug selection and careful monitoring of hemodynamic parameters.

Thus, the results of the present study are consistent with current literature data and confirm that the choice of an α1-adrenergic blocker in patients with BPH and diabetes mellitus should be individualized, taking into account symptom severity, urodynamic disturbances, comorbidities, and patient preferences.

Conclusion

1. The use of tamsulosin and silodosin in patients over 60 years of age with benign prostatic hyperplasia and diabetes mellitus is associated with a statistically significant improvement in urodynamic parameters and a reduction in the severity of lower urinary tract symptoms (LUTS) ($p<0.05$).
2. Silodosin demonstrates a statistically significant advantage over tamsulosin in terms of maximum and average urinary flow rates, reduction of post-void residual urine volume, improvement of LUTS severity, total IPSS score, and frequency of nocturia ($p<0.05$).
3. Tamsulosin is characterized by a more favorable profile regarding sexual adverse effects; however, it is more frequently associated with decreases in blood pressure and episodes of dizziness, which should be taken into account when treating patients with cardiovascular comorbidities.
4. The choice of an α1-adrenergic blocker in patients with benign prostatic hyperplasia and diabetes mellitus should be based on an individualized assessment of the clinical presentation, severity of urodynamic disorders, risk of adverse effects, and the patient's quality of life.
5. The obtained results confirm the feasibility of a differentiated approach to the pharmacological treatment of benign prostatic hyperplasia in patients with diabetes mellitus and may be applied in clinical practice

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