

The efficacy of tadalafil in managing chronic prostatitis/ chronic pelvic pain syndrome with erectile dysfunction

Tadalafilin kronik prostatit/kronik pelvik ağrı sendromu ve erektil disfonksiyon yönetimindeki etkinliği

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ABSTRACT

OBJECTIVE: Chronic Prostatitis/Chronic Pelvic Pain Syndrome (CP/ CPPS) is a common urological condition characterized by pelvic pain and urinary symptoms, significantly affecting the quality of life. This study evaluates the efficacy of Tadalafil, a phosphodiesterase type 5 inhibitor, as an adjunct therapy in patients with CP/ CPPS and concomitant erectile dysfunction (ED).

MATERIAL and METHODS: This retrospective study included 70 patients diagnosed with CP/ CPPS and ED who presented to Training and Research Hospital between January 2020 and June 2022. Patients were divided into two groups: Group 1 (n=35) received standard treatment (ciprofloxacin and diclofenac sodium), and Group 2 (n=35) received the same standard treatment plus Tadalafil 5 mg once daily for four weeks. Symptom scores were evaluated using the International Prostate Symptom Score (IPSS), NIH Chronic Prostatitis Symptom Index (NIH-CPSI), and International Index of Erectile Function (IIEF). Statistical analysis was performed using IBM Statistical Package for Social Sciences (SPSS) program version 25.0, with a p-value of <0.05 considered significant.

RESULTS: The baseline characteristics were comparable between the two groups. Group 2 showed significantly greater improvements in VAS pain scores, NIH-CPSI pain scores, NIH-CPSI urinary scores, IPSS, NIH-CPSI QoL scores, and IIEF scores compared to Group 1 (p<0.01 for all). These results suggest that Tadalafil significantly enhances pain relief, urinary symptom improvement, quality of life, and erectile function in CP/ CPPS patients with ED.

CONCLUSION: The addition of Tadalafil to the standard treatment regimen for CP/ CPPS significantly improves pain, urinary symptoms, quality of life, and erectile function. Tadalafil is an effective adjunct therapy for CP/ CPPS patients with concomitant ED, offering a comprehensive approach to managing this challenging condition.

Keywords: tadalafil, PDE5-inhibitors, prostatitis, pelvic pain, CP/ CPPS, prostatic pain

ÖZ

AMAÇ: Kronik Prostatit/Kronik Pelvik Ağrı Sendromu (CP/ CPPS), pelvik ağrı ve idrar semptomlarıyla karakterize, yaygın görülen bir ürolojik durumdur ve yaşam kalitesini önemli ölçüde etkilemektedir. Bu çalışmada, CP/ CPPS ve eşlik eden erektil disfonksiyonu (ED) olan hastalarda fosfodiesteraz tip 5 inhibitörü olan Tadalafil'in ek tedavi olarak etkinliği değerlendirilmiştir.

GEREÇ ve YÖNTEMLER: Bu retrospektif çalışmaya, Ocak 2020 ile Haziran 2022 tarihleri arasında Eğitim ve Araştırma Hastanesi'ne başvuran CP/ CPPS ve ED tanısı almış 70 hasta dâhil edilmiştir. Hastalar iki gruba ayrılmıştır: Grup 1 (n=35) standart tedavi (siprofloksasin ve diklofenak sodyum) alırken, Grup 2 (n=35) aynı standart tedaviye ek olarak dört hafta boyunca günde bir kez 5 mg Tadalafil almıştır. Semptom skorları Uluslararası Prostat Semptom Skoru (IPSS), NIH Kronik Prostatit Semptom İndeksi (NIH-CPSI) ve Uluslararası Eretil Fonksiyon İndeksi (IIEF) kullanılarak değerlendirilmiştir. İstatistiksel analiz, IBM Sosyal Bilimlerde İstatistik Paket Programı (SPSS) sürüm 25.0 ile yapılmış olup, p<0,05 değeri anlamlı kabul edilmiştir.

BULGULAR: İki grup arasında başlangıç özellikleri karşılaştırılabilir düzeydeydi. Grup 2, Grup 1'e kıyasla VAS ağrı skoru, NIH-CPSI ağrı skoru, NIH-CPSI idrar skoru, IPSS, NIH-CPSI yaşam kalitesi skoru ve IIEF skorlarında anlamlı derecede daha fazla iyileşme göstermiştir (hepsi için p<0,01). Bu sonuçlar, Tadalafil'in CP/ CPPS'li ve ED'li hastalarda ağrı, idrar semptomları, yaşam kalitesi ve erektil fonksiyon iyileşmesini önemli ölçüde artırdığını göstermektedir.

SONUÇ: Tadalafil'in CP/ CPPS için standart tedavi rejimine eklenmesi, ağrı, idrar semptomları, yaşam kalitesi ve erektil fonksiyon üzerinde önemli iyileşmeler sağlamaktadır. Tadalafil, eşlik eden ED'li CP/ CPPS hastaları için etkili bir ek tedavi seçeneği sunmakta ve bu zorlu durumun yönetiminde kapsamlı bir yaklaşım sunmaktadır.

Anahtar Kelimeler: tadalafil, prostatit, CP/ CPPS, tadalafil, PDE5-inhibitörleri, pelvik ağrı

INTRODUCTION

Chronic Prostatitis/Chronic Pelvic Pain Syndrome (CP/ CPPS) is a prevalent and challenging condition encountered in urology clinics. Characterized by lower urinary tract symptoms (LUTS) and pain in the pelvic region, CP/ CPPS significantly impacts patients quality of life. According to the National Institutes of Health (NIH),

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prostatitis is classified into four categories, with CP/CPPS falling under category III, which is further divided into two subtypes: type IIIA (inflammatory) and type IIIB (non-inflammatory).^[1] In the United States, the prevalence of CP/CPPS is reported to be around 8.2%, making it a significant concern among men under 50 years of age.^[2]

The etiology and pathophysiology of CP/CPPS are not completely understood, making it a multifactorial disease. Proposed mechanisms include infection, inflammation, autoimmune responses, and neurogenic factors.^[3] Despite numerous studies, a definitive cause for CP/CPPS remains elusive, and the condition is often associated with psychological factors such as stress and anxiety, which can exacerbate symptoms.^[4]

Various treatment modalities are employed in managing CP/CPPS, reflecting its complex etiology. These include antibiotics, alpha-blockers, anti-inflammatory drugs, phytotherapy, and neuromodulatory treatments.^[5] One promising approach involves the use of phosphodiesterase type 5 inhibitors (PDE-5Is) such as Tadalafil.^[6] Initially developed for erectile dysfunction (ED), Tadalafil has shown therapeutic potential in CP/CPPS by improving LUTS and erectile function.^[7] Its mechanism involves enhancing smooth muscle relaxation in the bladder and prostate through increased cyclic guanosine monophosphate (cGMP) levels, mediated by nitric oxide (NO).^[7]

Tadalafil's effectiveness in treating CP/CPPS has been supported by various clinical trials. These studies indicate that Tadalafil not only alleviates urinary symptoms but also has anti-inflammatory effects that contribute to the management of CP/CPPS.^[8] This dual benefit is particularly significant given the frequent coexistence of CP/CPPS and ED in patients. Approximately 56% of men with CP/CPPS experience some degree of ED, further complicating their treatment.^[9]

In addition to pharmacological treatments, lifestyle modifications have been shown to benefit men with ED, especially in those with modifiable risk factors such as smoking, obesity, sedentary lifestyle, and stress.^[10] Studies indicate that incorporating lifestyle changes like regular physical activity, dietary adjustments, weight management, and smoking cessation can positively influence erectile function by improving cardiovascular health and reducing oxidative stress and endothelial dysfunction.^[10] Such approaches complement pharmacological treatments and may be recommended as part of comprehensive ED management.

The aim of this study is to evaluate the efficacy of Tadalafil in patients diagnosed with CP/CPPS and concomitant

ED. We hypothesize that adding Tadalafil to the treatment regimen for CP/CPPS will result in significant improvement in both urinary and sexual symptoms, thus enhancing overall patient outcomes.

MATERIAL and METHODS

Study Design and Participants

This retrospective study included patients diagnosed with chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) and accompanying erectile dysfunction (ED) who presented to the hospital between January 2020 and June 2022. All participants received a standard treatment of antibiotics and anti-inflammatory therapy for CP/CPPS. However, patients were further classified based on their ED management into two groups: Group 1 (n=35) consisted of patients who did not receive additional ED-specific pharmacotherapy but were advised on lifestyle modifications for ED management. Group 2 (n=35) included those who, along with standard CP/CPPS treatment, opted for ED management with Tadalafil 5 mg once daily for four weeks. This classification was retrospectively designed based on patient treatment choices. The study received ethical approval from the Kütahya Health Sciences University Ethics Committee.

Inclusion and Exclusion Criteria

Inclusion criteria were:

- Male patients aged 18–65 years.
- Diagnosed with CP/CPPS (Type III) according to NIH criteria.
- Experiencing erectile dysfunction as defined by an International Index of Erectile Function (IIEF) score of <25.
- No use of PDE-5 inhibitors or other specific treatments for ED in the last six months.

Exclusion criteria included:

- Bacterial prostatitis (NIH Category I and II). Diagnosed based on negative urine cultures and clinical findings
- Previous prostate surgery.
- History of urethral stricture or other urological conditions that could affect the study results.
- Severe cardiovascular diseases or other comorbidities contraindicating PDE-5 inhibitors.

Treatment Protocol

Group 1 received standard treatment, which included oral ciprofloxacin 500 mg twice daily and diclofenac sodium

75 mg once daily for four weeks. Group 2 received the same standard treatment plus Tadalafil 5 mg once daily for four weeks. All patients were evaluated before and after the treatment period using several standardized tools. Erectile function was assessed with the 5-item International Index of Erectile Function (IIEF-5) questionnaire.^[11] Pain intensity was measured using the Visual Analog Scale (VAS)^[12], a validated tool that rates pain on a scale of 0 (no pain) to 10 (worst pain imaginable). Urinary symptoms, including frequency, urgency, and nocturia, were evaluated using the International Prostate Symptom Score (IPSS)^[13], which ranges from 0 to 35. Additionally, the NIH Chronic Prostatitis Symptom Index (NIH-CPSI) was used to assess the severity of symptoms associated with chronic prostatitis, including pain, urinary symptoms, and the impact on quality of life.^[14]

STATISTICS

The statistical analysis for the study data was conducted using IBM Statistical Package for Social Sciences (SPSS) program version 26 (IBM Corp., Armonk, NY, USA). The assessment of normality for the variables was carried out using the Kolmogorov-Smirnov or Shapiro-Wilk tests. Continuous variables with a normal distribution were compared between groups using the t-test, while those without normal distribution were analyzed using the Mann-Whitney U test. For categorical variables, the Pearson chi-square test and Fisher's exact test were applied for normally distributed data, whereas the Wilcoxon signed-rank test was used for non-normally distributed data. To evaluate the changes within dependent groups before and after treatment, repeated measures ANOVA was performed. Additionally, comparisons of pre- and post-treatment conditions between independent groups were conducted using either the Student's t-test or the Mann-Whitney U test. A p-value of less than 0.05 was considered to indicate statistical significance. A power analysis conducted during the study design phase indicated that a sample size of 70 participants would provide adequate statistical power to detect significant differences between groups.

RESULTS

Baseline Characteristics

The baseline characteristics of the study participants and symptom scores are summarized in Table 1. The two groups were comparable in terms of age, duration of CP/CPPS, and baseline symptom scores (IPSS, NIH-CPSI, and IIEF). No statistically significant differences were observed

between groups, ensuring a balanced distribution of demographic and clinical parameters.

Symptom Scores

The mean changes in symptom scores before and after the treatment are presented in Table 1 and Fig. 1.

Pain Scores (VAS and NIH-CPSI Pain)

In Group 2, which received Tadalafil, the mean Visual Analog Scale (VAS) pain scores decreased significantly more compared to Group 1 ($p < 0.01$). Similarly, the NIH-CPSI pain scores showed a statistically significant greater reduction in Group 2 compared to Group 1 ($p < 0.01$) (Fig. 1). This indicates a superior effect of Tadalafil in alleviating pain associated with CP/CPPS.

Urinary Symptoms (NIH-CPSI Urinary and IPSS)

Both groups showed improvement in urinary symptoms after the treatment. However, Group 2 had a significantly greater reduction in NIH-CPSI urinary symptom scores and IPSS scores compared to Group 1 ($p < 0.01$) (Fig. 1). This suggests that Tadalafil contributes to a more pronounced improvement in urinary symptoms when added to the standard treatment regimen.

Quality of Life (NIH-CPSI QoL)

The quality of life scores, measured by the NIH-CPSI QoL subscale, improved significantly in both groups. Group 2 exhibited a significantly greater improvement compared to Group 1 ($p < 0.01$) (Fig. 1). This enhancement in quality of life underscores the additional benefit of Tadalafil in managing CP/CPPS.

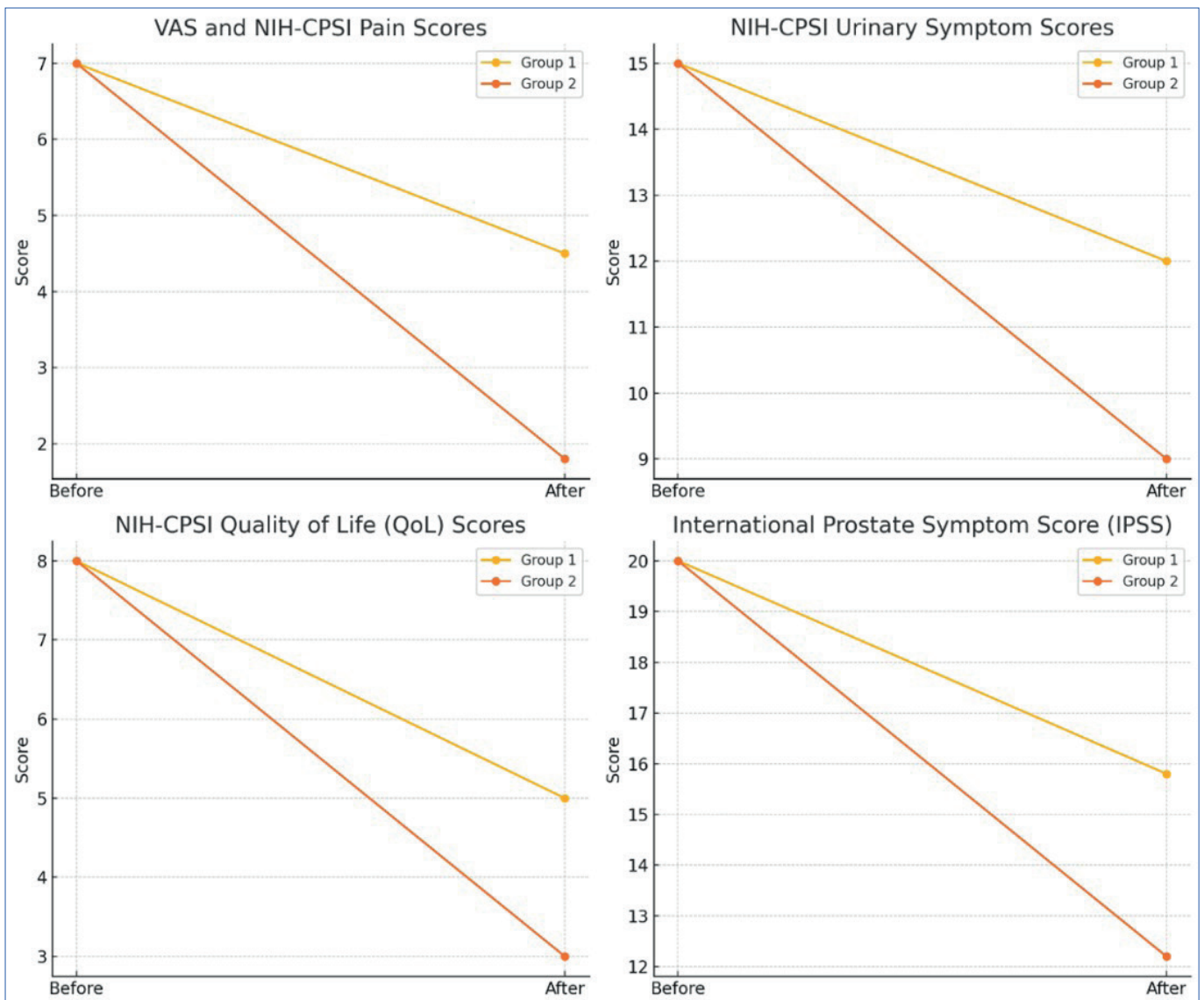
Erectile Function (IIEF)

The International Index of Erectile Function (IIEF) scores increased significantly in Group 2 after the treatment ($p < 0.01$). In contrast, Group 1 showed minimal improvement, which was not statistically significant (Fig. 1). This indicates that Tadalafil effectively improves erectile function in patients with CP/CPPS and concomitant ED.

Overall, these results suggest that Tadalafil is a valuable adjunct therapy in the management of CP/CPPS, providing benefits beyond standard treatment alone. Its dual action in improving both urinary and erectile function, along with enhancing quality of life, makes it a promising therapeutic option for patients suffering from this challenging condition.

Table 1. The baseline characteristics of the study participants

	Before treatment (mean)	After treatment (mean)	Change from baseline (%)	P value
VAS score Group I	6.23±1.62	3.89±1.62	38%	<0.01
VAS score Group II	5.83±1.5	1.71±0.86	71%	<0.01
NIH-CPSI pain Group I	13.69±3.38	8.68±3.64	37%	<0.01
NIH-CPSI pain Group II	12.51±2.87	4±2.1	68%	<0.01
NIH-CPSI urinary symptoms Group I	6.06±2.55	3.77±2.34	38%	<0.01
NIH-CPSI urinary symptoms Group II	5.09±2.62	1.74±1.35	66%	<0.01
NIHCPSI QOL Group I	7.83±2.44	4.4±2.29	44%	<0.01
NIHCPSI QOL Group II	6.8±2.34	2.17±1.7	68%	<0.01
IPSS Group I	14.28±4.77	9.88±4.76	31%	<0.01
IPSS Group II	12.68±5.82	4.37±3.01	66%	<0.01
IIEF Group I	13.29±3.51	15.54±3.24	-17%	<0.01
IIEF Group II	12.94±3.16	22.54±3.35	-74%	<0.01

**Figure 1.** Symptom Score Changes Before and After Treatment. In the upper part, from left to right, VAS and NIH-CPSI pain parameters, NIH-CPSI urinary symptom scores; At the bottom, from left to right, NIH-CPSI Quality of Life scores and IPSS scores.

DISCUSSION

This study evaluated the efficacy of Tadalafil as an adjunct therapy in the treatment of Chronic Prostatitis/Chronic Pelvic Pain Syndrome (CP/CPPS) with concomitant erectile dysfunction (ED). Our findings demonstrate that the addition of Tadalafil to the standard treatment regimen significantly improves pain, urinary symptoms, quality of life, and erectile function compared to standard treatment alone. The 5 mg dose of Tadalafil was chosen based on its approval for daily use in managing erectile dysfunction and its demonstrated efficacy in improving lower urinary tract symptoms.^[15]

The significant reduction in pain scores in the Tadalafil group (Group 2) is one of the most notable findings of this study. Both the Visual Analog Scale (VAS) and NIH-CPSI pain scores showed a greater decrease in Group 2 compared to Group 1. The pain relief effect may be partially due to Tadalafil's anti-inflammatory properties, which are thought to alleviate urological inflammation. This aligns with Zhang et al.'s findings, which report anti-inflammatory effects from PDE-5 inhibitors in urological tissue.^[16] However, it should be noted that placebo effects are common in ED treatment studies, as shown by literature on high placebo response rates among ED patients. This factor may contribute to perceived improvements in CP/CPPS pain, warranting further exploration in placebo-controlled studies.^[17]

Furthermore, our study observed a significant improvement in urinary symptoms in the Tadalafil group, as indicated by reductions in NIH-CPSI urinary symptom scores and IPSS scores. PDE-5 inhibitors like Tadalafil may relax smooth muscle in the bladder and prostate, potentially easing LUTS symptoms via increased cGMP levels. Although CP/CPPS and BPH are distinct, the mechanisms of symptom improvement may overlap, suggesting Tadalafil's action could benefit both. Previous work by McVary et al. on BPH and Tadalafil supports these findings^[7], but more focused studies on CP/CPPS are needed to validate this observation.

The efficacy of phosphodiesterase type 5 inhibitors (PDE-5Is) in improving lower urinary tract symptoms (LUTS) has been previously established, particularly in the context of benign prostatic hyperplasia (BPH). Studies suggest that PDE-5Is, including Tadalafil, may contribute to LUTS relief by enhancing smooth muscle relaxation, restoring perfusion, and exerting anti-inflammatory effects in the prostate and bladder tissues.^[18]

The quality of life (QoL) improvements observed in the Tadalafil group further reflect the drug's potential role in

CP/CPPS management. ED, which is common among CP/CPPS patients, substantially affects mental health and quality of life.^[15] Our findings suggest that addressing ED with Tadalafil might contribute to an overall QoL improvement by simultaneously relieving LUTS and enhancing erectile function. Consistent with Kaplan et al.'s work on QoL improvements in LUTS and ED patients using PDE-5 inhibitors, this dual effect highlights the value of Tadalafil in comprehensive CP/CPPS management.^[19]

The increase in IIEF scores in the Tadalafil group highlights its efficacy in treating ED in patients with CP/CPPS. Given the high prevalence of ED in CP/CPPS patients (up to 56%)^[9], addressing this comorbidity is essential for comprehensive patient care. Additionally, lifestyle interventions, such as dietary adjustments, exercise, and smoking cessation, have shown positive effects on ED management, as highlighted in recent literature.^[10] These measures could support pharmacotherapy, particularly in CP/CPPS patients who prefer non-pharmacological options or as adjuncts to Tadalafil.

Our findings are consistent with existing literature that demonstrates the efficacy of Tadalafil in managing CP/CPPS symptoms. Studies by both McVary et al. and Zhang et al. have shown that Tadalafil significantly reduces LUTS and improves sexual function in patients with BPH and CP/CPPS, respectively.^[7,17] This alignment with previous studies underscores Tadalafil's potential as an effective component of multimodal treatment strategies for CP/CPPS, despite its primary use in ED treatment.

The clinical implications of this study are significant. First, Tadalafil can be considered a valuable addition to the multimodal treatment approach for CP/CPPS, providing benefits that extend beyond pain relief. Second, addressing ED in CP/CPPS patients not only improves sexual health but also enhances overall treatment satisfaction and quality of life. Clinicians should consider incorporating Tadalafil into treatment plans for patients with CP/CPPS and ED, particularly those who have not responded adequately to standard therapies. This dual-action treatment offers a comprehensive approach to managing the multifaceted symptoms of CP/CPPS.

While our study provides valuable insights, it has some limitations. The retrospective design and relatively small sample size may limit the generalizability of the findings. Future studies with larger, randomized controlled trials are needed to confirm these results and explore the long-term effects of Tadalafil in CP/CPPS patients. Additionally, further research is warranted to understand the underlying mechanisms by which Tadalafil exerts its therapeutic effects

in this patient population. Prospective studies could also investigate patient adherence and long-term outcomes, providing a broader perspective on the clinical utility of Tadalafil in CP/CPPS treatment.

In conclusion, the addition of Tadalafil to the standard treatment regimen for CP/CPPS significantly improves pain, urinary symptoms, quality of life, and erectile function. These findings suggest that Tadalafil is an effective adjunct therapy for CP/CPPS patients with concomitant ED. Clinicians should consider its use to enhance patient outcomes and overall quality of life. Further research is needed to validate these findings and explore the long-term benefits of Tadalafil in managing CP/CPPS.

By integrating these comprehensive findings, we highlight the multifaceted benefits of Tadalafil, offering a holistic treatment approach for CP/CPPS patients. This study adds to the growing body of evidence supporting the use of PDE-5 inhibitors in urological conditions, paving the way for improved patient care and outcomes.

CONCLUSIONS

The addition of Tadalafil to the standard treatment regimen for CP/CPPS significantly improves pain, urinary symptoms, quality of life, and erectile function. These findings suggest that Tadalafil is an effective adjunct therapy for patients with CP/CPPS and concomitant ED. Clinicians should consider its use to enhance patient outcomes and overall quality of life. Further research is needed to confirm these results and explore the long-term benefits of Tadalafil in managing CP/CPPS.

Ethics Committee Approval

The study was approved by Kütahya Health Sciences University Non-Interventional Clinical Research Ethics Committee. (date and number of approval: 22.06.2022/2022/07).

Peer-review

Externally peer-reviewed.

Conflict of Interest

No conflict of interest was declared by the authors.

Financial Disclosure

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