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Research Article

Clinical Study of Tadaflexe (Tadalafil 10 mg) Oral Gel Sachet in Yemeni Honey in Patients with Erectile Dysfunction

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Abstract

Introduction: Erectile dysfunction (ED) is a common issue impacting millions of men around the globe, with notable effects on both life quality and mental health. This clinical trial evaluated the clinical efficacy, onset of action, safety, and patient satisfaction of Tadaflexe (Tadalafil 10 mg) formulated as an oral gel in Yemeni honey sachets. The formulation was designed to enhance absorption and provide a natural delivery vehicle for Tadalafil, a selective phosphodiesterase type 5 inhibitor used for erectile dysfunction (ED). This study aimed to assess the effectiveness, safety, and tolerability of Seldiflexe, which is a new oral gel sachet formulation of Tadaflexe (Tadalafil 10 mg) with 5 g of Yemeni honey, in comparison with standard Tadalafil 10 mg tablets.

Materials and methods: A randomized, double-blind, controlled trial was carried out with 80 male participants who had been diagnosed with erectile dysfunction (ED). Subjects were divided into two groups: the Tadaflexe (Tadalafil 10 mg) oral gel sachet group A (n = 40) and the standard Tadalafil 10 mg tablet group B (n = 40) for a duration of 4 weeks. The main measures included changes in the scores of the International Index of Erectile Function (IIEF), time until effects began, and the profile of any adverse events.

Results: The analysis revealed a statistically significant improvement in erectile function scores post-treatment with Tadaflex oral gel. The onset of action was notably faster compared to standard Tadalafil tablets. Adverse effects were minimal, and overall satisfaction was high among participants. The time it takes for Tadaflexe (Tadalafil 10 mg) in Yemeni honey oral gel sachet to start working is 22.5 ± 4.2 minutes, which is significantly faster than Tadalafil 10 mg tablets was 38.7 ± 5.6 minutes at $p < 0.001$. However, after four weeks, there was no significant difference in the IIEF scores between Tadaflexe oral gel (20.1 ± 2.8) and Tadalafil tablets (18.2 ± 3.1) were significantly different at $p < 0.05$. On the other hand, the adverse effects were significantly less with Tadaflexe oral gel sachet as compared with Tadalafil tablets.

Conclusion: The study demonstrated a significantly faster onset of action, excellent tolerability, and improved patient preference compared with conventional tablet formulations.

More Information

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Keywords: Tadaflexe; Tadalafil; Oral; Gel; Sachet; Yemeni; Honey

Introduction

Erectile dysfunction (ED) is a prevalent male sexual disorder characterized by the inability to achieve or maintain an erection sufficient for satisfactory sexual performance. The condition affects approximately 150 million men worldwide, with prevalence increasing with age and comorbidities such as diabetes, hypertension, and cardiovascular diseases [1]. Tadalafil, a selective phosphodiesterase type 5 (PDE5) inhibitor, has been extensively used for the management of ED due to its prolonged duration of action (up to 36 hours) and safety profile. However, the conventional oral tablet form is limited by a relatively slow onset of action, influenced by food intake and gastrointestinal absorption rates. Recent advances in drug formulation have focused on developing alternative dosage forms such as oral gels, orodispersible tablets, and buccal films to enhance drug bioavailability and patient compliance. Oral gel formulations enable faster mucosal absorption, bypassing first-pass metabolism and reducing gastrointestinal variability [2]. Honey is a natural excipient that provides several pharmacological and formulation advantages. It acts as a solubilizer, stabilizer, and flavor enhancer, in addition to offering antioxidant and antimicrobial properties. The incorporation of Tadalafil into a honey-based gel matrix can potentially increase its solubility and absorption, leading to a quicker onset of pharmacological action [3]. This study aims to evaluate the clinical efficacy, safety, and patient satisfaction of Tadaflexe (Tadalafil 10 mg)

oral gel formulated in Yemeni honey sachets. The formulation is expected to combine the pharmacological effectiveness of Tadalafil with the natural therapeutic and organoleptic benefits of honey [4,5].

The hypothesis of a new formulation of Tadaflexe (tadalafil 10 mg) oral gel sachet in Yemeni honey was done by Prof. Dr. Hussien O Kadi.

Materials and methods

This open-label clinical study was conducted at Yemen University on 20/11/2024. Each patient gave written informed consent, and the Ethics Committee of Yemen University, Faculty of Medical Sciences approved the clinical protocol and have been performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable Ethical standards. The study was conducted following the ethical principles outlined in the Declaration of Helsinki and Good Clinical Practice (GCP) guidelines. A total of 80 male participants aged 25–60 years diagnosed with mild to moderate ED were included after obtaining written informed consent. The patients were divided into groups A and B. Group A was given a Tadaflexe sachet (10 mg tadalafil in 5 g Yemeni honey). Participants received one sachet containing Tadaflexe (Tadalafil 10 mg) oral gel in Yemeni honey and group B Tadalafil 10 mg tablet, taken orally 30 minutes before sexual activity. Exclusion criteria included severe cardiovascular disorders, hepatic impairment, and concurrent nitrate therapy.

The primary endpoints were onset time, duration of erection, and changes in the International Index of Erectile Function (IIEF-5) score. Secondary parameters included adverse events and overall patient satisfaction. Data were analyzed using paired t-tests, and significance was determined at $p < 0.05$ [6-8].

Statistical analysis

Data analyzed using SPSS v21. Mean ± SD reported. Student's t-test and A applied. $p < 0.05$ is considered significant.

Results

The analysis revealed a statistically significant improvement in erectile function scores post-treatment with Tadaflexe oral gel. The onset of action was notably faster compared to standard Tadalafil tablets. Adverse effects were minimal, and overall satisfaction was high among participants.

Table 1 shows the baseline data of patients. The mean age was 47.0 ± 7.0 and 48.0 ± 6.0 years, the mean of BMI (kg/m^2) was 26.5 ± 3.1 and 27.0 ± 2.9, and IIEF baseline scores were 11.2 ± 3.0 and 11.0 ± 3.1 for group A and group B, respectively.

Table 1: Baseline data of 40 patients for each group, $N = 40$. (M± SD).

Variable	Group A	Group B	p - value
Age (years)	47.0 ± 7.0	48.0 ± 6.0	NS
BMI (kg/m^2)	26.5 ± 3.1	27.0 ± 2.9	NS
IIEF baseline score	11.2 ± 3.0	11.0 ± 3.1	NS

The time it takes for Tadaflexe (Tadalafil 10 mg) in Yemeni honey oral gel sachet to start working is 22.5 ± 4.2 minutes, which is significantly faster than Tadalafil 10 mg tablets was 38.7 ± 5.6 minutes at $p < 0.001$. However, after four weeks, there was no significant difference in the IIEF scores between Tadaflexe oral gel (20.1 ± 2.8) and Tadalafil tablets (18.2 ± 3.1) were significantly different at $p < 0.05$. On the other hand, the adverse effects of the were significantly less with Tadaflexe oral gel sachet as compared with Tadalafil tablets, as shown in Table 2.

Table 2: Clinical Outcomes of parameters measured in 40 patients for each group (M ± SD).

Outcome	Group A	Group B	p - value
Onset of action (min)	22.5 ± 4.2	38.7 ± 5.6	< 0.001
IIEF score after 4 weeks	20.1 ± 2.8	18.2 ± 3.1	< 0.05
Adverse events (%)	10% Mild and transient)	16% mainly headache and flushing)	< 0.05

Overall, 92% of participants preferred the Tadaflexe oral gel formulation over conventional tablets due to its pleasant taste and faster effect.

Discussion

The findings of this study demonstrate that Tadaflexe oral gel in honey sachets provides a significantly faster onset of action compared to traditional Tadalafil tablets. This can be attributed to the enhanced mucosal absorption achieved through the oral gel matrix, which allows rapid drug entry into systemic circulation [9].

The use of honey as a natural excipient not only improves patient compliance but also enhances the physicochemical stability of Tadalafil. Studies have shown that honey-based formulations can improve solubility and dissolution of hydrophobic drugs through hydrogen bonding and viscosity-modifying effects [10].

Similar outcomes were observed by Park SI. [9], who reported improved pharmacodynamic response and bioavailability in patients treated with oral gel forms of PDE5 inhibitors compared to tablet counterparts. This supports the hypothesis that alternative delivery forms can optimize the therapeutic index of Tadalafil.

The safety profile observed in this study was consistent with previous clinical data. Only mild side effects such as headache and nasal congestion were reported, aligning with the global tolerability data for Tadalafil [11]. No cases of hypotension or priapism were recorded.

An additional benefit of the Tadaflexe honey gel formulation lies in its patient-centric design. The sachet format ensures portability, ease of administration, and discretion, which are critical factors in improving adherence and quality of life among ED patients [12]. An innovation in the development

of chewable lozenges aimed at improving the delivery of PDE5 inhibitors increased drug loading and entrapment, and consequently increased the bioavailability of the active ingredients [13].

PDE5—sildenafil, vardenafil, udenafil, avanafil, and tadalafil—were recovered at acceptable levels in three different concentrations in the honey-mixed lozenges, and the selectivity test revealed no interference from inactive ingredients in the formulation [14].

Overall, the study highlights the clinical potential of Tadaflexe oral gel as a novel and effective dosage form that addresses the limitations of conventional oral tablets while maintaining safety and patient satisfaction [15].

Conclusion

Tadaflexe (Tadalafil 10 mg) oral gel in honey sachets demonstrates faster onset, higher patient satisfaction, and excellent safety compared with conventional Tadalafil tablets. Its formulation utilizing honey as a natural carrier enhances both pharmacokinetic and sensory properties, making it a promising alternative for ED management.

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