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REVIEW

Is Silodosin better than Tadalafil as a medical expulsive therapy in lower ureter stones?

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Summary *Objective: This meta-analysis aims to compare the efficacy and safety of Tadalafil and Silodosin as Medical Expulsive Therapy (MET) for lower ureteric stones below 10mm. The study also assesses the incidence of adverse effects associated with each drug.*

Methods: A comprehensive search of electronic databases was conducted up to October, 2024. The study included randomized controlled trials (RCTs) and cohort studies that compared Tadalafil and Silodosin in patients with lower ureteric stones (5-10 mm). The primary outcomes assessed were stone expulsion time (SET), stone expulsion rate (SER), and adverse effects. Data were analyzed using a random-effects model for heterogeneity and a fixed-effect model for non-heterogeneity.

Results: Eight studies involving 797 patients were included. The pooled analysis showed no significant difference in SET between Tadalafil and Silodosin (MD = 0.15, 95% CI [-0.28, 0.57], p = 0.50), with significant heterogeneity. Similarly, the pooled analysis showed no significant difference in SER between the two drugs (RR = 0.92, 95% CI [0.80 to 1.05], p = 0.22), with heterogeneity. However, after excluding one study, Silodosin was favored over Tadalafil for SER (RR 0.88, 95% CI [0.79 to 0.98], p = 0.02). There were no significant differences in headache, backache, or dizziness. Silodosin was associated with a higher incidence of orthostatic hypotension, but this was resolved by excluding one study. A significant difference for abnormal ejaculation favored Tadalafil (RR = 0.16, 95% CI [0.09 to 0.29], p = 0.01).

Conclusions: While the pooled results initially showed no significant difference in SET and SER, Silodosin demonstrated a superior stone expulsion rate after adjusting for heterogeneity Silodosin showed a trend towards shorter SET. However, Silodosin was associated with a higher risk of orthostatic hypotension and abnormal ejaculation. Further high-quality RCTs with larger sample sizes are needed to confirm these findings.

KEY WORDS: *Ureter stones; Tadalafil; Silodosin; Alpha blockers; Medical Expulsive Therapy.*

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INTRODUCTION

Despite recent advances of endoscopic techniques for management of urinary stones, the prevalence of this condition continues to increase. According to the recent epidemiologic studies, the incidence of urolithiasis increased from 77.78 million incident cases in 1990 to 115.55 million in 2019 (1). Highest incidence rate of kidney stones were reported in Saudi Arabia, Kuwait, South Korea, China, Thailand, Spain, Greece and the United States of America which raise concerns about the cause of kidney stone and whether it is linked to certain foods, faulty habitats and the nature of these countries (2, 3). Medical treatment of kidney stones includes life style modification, high water intake, weight reduction and exercise (4). Oral or intravenous *non-steroidal anti-inflammatory drugs* (NSAIDs) may be used to relieve pain. *Medical Expulsive Therapy* (MET) with alpha blockers has showed promising results on stone expulsion with Tamsulosin being the most commonly used of this family of drugs (5). Silodosin is a selective alpha blocker drug that works by binding to the extracellular domain of the alpha receptors, which inhibits activation of G protein and prevents phosphorylation of phospholipase C, giving a net result of smooth muscle relaxation (6). Silodosin is 50 times more potent and selective on alpha 1 receptors than Tamsulosin, which made most urologists and researchers believe that it might be more useful than Tamsulosin considering the specifically high density of alpha 1 receptors in the lower ureter (7). Tadalafil also is a promising drug for MET that acts by inhibiting the *phosphodiesterase-5 Enzyme* (PDE-5) leading to accumulation of cyclic guanosine mono phosphate and subsequent smooth muscle relaxation (8). Although the exact mechanism of Tadalafil on lower ureter relaxation is not yet fully understood, it has proven to be a considerable option for MET especially in patients with erectile dysfunction (9).

Natural stone passage is enabled with Tadalafil by ureter lumen dilation, whereas alpha-1 adrenergic receptor antagonists induce stone passage by reducing muscle spasms (10, 11).

In this study we aimed to compare Tadalafil and Silodosin for MET in lower ureter stones below 10 mm through a comprehensive systematic review and meta-analysis and to assess the incidence of any adverse effects for each drug.

Materials and methods

We adhered to the preferred reporting items for systematic reviews and meta-analyses (PRISMA statement) (12). All steps were completed per the Cochrane Handbook of Systematic Reviews and Meta-analysis (13). This study was prospectively registered on PROSPERO with the study ID (CRD42024597302).

Search strategy and data collection

A search of electronic databases including *PubMed, Scopus, Cochrane, Science Direct, EMBASE, Web of Science, EBSCO* and *Google Scholar* has been performed until 01/10/2024 using the following keywords ("*Silodosin*" OR "*Alpha blocker*" OR "*Adrenergic alpha Antagonists*" OR "*Adrenergic alpha-Antagonists*" [Mesh] OR "*Antihypertensive*") AND ("*Tadalafil*" OR "*phosphodiesterase 5 inhibitor*" OR "*PDE5 inhibitors*") AND ("*ureteric stones*" OR "*distal ureter stones*" OR "*lower ureter stones*" [Mesh]).

Selection criteria

To screen the results of the literature search, we used Rayyan software (14). Two stages of screening were used for studies. Title and abstract screening was the initial stage. The second stage involved screening the chosen abstracts for full-text articles and resolving discrepancies through discussion. Cohort studies and RCTs that were reported on our PICO model as follows.

P (Patient/Problem): Patients with lower ureteric stones 5 to 10 mm in size; I (Intervention): Studies where Tadalafil was administered; C (Comparator): Studies where Silodosin was administered; O (Outcome): Stone size, *Stone Expulsion Time* (SET), *Stone Expulsion Rate* (SER), pain episodes, and side effects; S (Study Design): *Randomized control clinical trials* (RCTs) and Cohort studies.

Studies with inadequate or deficient data for extraction were not included. Studies with overlapping datasets, case-control studies, non-clinical studies, reviews, book chapters, case reports, case series, theses, editorials, letters, conference papers, and non-English studies were excluded. Additionally, non-randomized controlled trials were not included.

Data extraction

We used Google spreadsheets for data extraction. The spreadsheet file was accessible to all authors. All authors took part in data extraction. Extracted data were mainly divided into four domains: 1) study characteristics, 2) characteristics of the included studies' population, 3) risk of bias domains, and 4) study outcomes.

Summary: study ID (first author-publication year), study design, location, year, population, intervention, comparator, outcome, key findings

Baseline: study arms, age (years), stone size (mm), body mass index (kg/m²), side (N (%), stone expulsion time (days), stone expulsion rate (%), analgesic dose (MB).

Outcomes: SET, SER, headache, backache, dizziness, orthostatic hypotension, abnormal ejaculation, pain episodes.

Quality assessment

The Cochrane *risk of bias* (ROB 2) tool was used to assess the quality of the studies that were part of this systematic review (15). There are seven study domains in the Cochrane ROB: 1) random sequence generation, 2) allocation concealment, 3) blinding of the investigators and patients, 4) blinding of the outcome assessors, 5) incomplete outcome data, 6) selective outcome reporting, and 7) other sources of bias.

The study was classified as "*low risk*," "*high risk*," or "*unclear*" in each domain; disagreements were settled through discussion. *Newcastle-Ottawa Scale* (NOS) was used for observational cohort studies.

Statistical analysis

We carried out statistical analysis of the included studies using an online website called "*metaanalysisonline*" with random effect model for the heterogeneity results and a fixed effect for non-heterogeneity results. Continuous data were exhibited as *mean difference* (MD) and 95% *confidence interval* (CI), while dichotomous data was exhibited as *risk ratio* (RR) and 95% CI. Heterogeneity evaluated using *I-squared* (I^2) and *Chi-square* (chi^2) tests (16).

We considered heterogeneity significant if I^2 was more than (45) % and the P-value of Chi^2 was less than 0.1. The random-effect model and sensitivity analysis were used for significant heterogeneity.

Results

Literature search results and characteristics of the included studies

We identified 176 studies through a database search. Following the removal of duplicates, 96 articles proceeded to the next review stage. Our meta-analysis included 8 studies after screening abstracts and full texts; this process is depicted in the PRISMA flow diagram Figure 1. Three observational studies and five *randomized controlled trials* (RCTs) formed the basis of our meta-analysis. These studies compared Tadalafil and Silodosin to determine how they affected the rate and time of stone expulsion.

Table 1 (***see supplementary material***) provides details on the studies included in this analysis, which were carried out between 2014 and 2024 across Egypt, India, Tunisia, and Turkey. A total of 797 patients with lower ureteric stones was included in these eight studies. The mean age of participants was 40.20 years for the Tadalafil groups and 39.6 years for the Silodosin groups, with a mean stone size of 6.7 mm. The intervention lasted between three and six weeks. Table 2 (***see supplementary material***) presents the characteristics of the study populations. Table 3 (***see supplementary material***) summarizes characteristics of adverse events.

Risk of bias in the included studies

The assessment of the quality of the included studies is demonstrated in Figure 2. We utilized the Cochrane *Risk of Bias 2* (ROB2) tool for randomized trials and the *Newcastle-Ottawa Scale* (NOS) for observational cohort studies. Our assessment revealed that two RCTs had a low risk of bias, while three studies showed some concerns.

The three observational cohort studies were rated 7 points, and one was rated 8 points indicating a low risk of bias (Table 4, ***see supplementary material***).

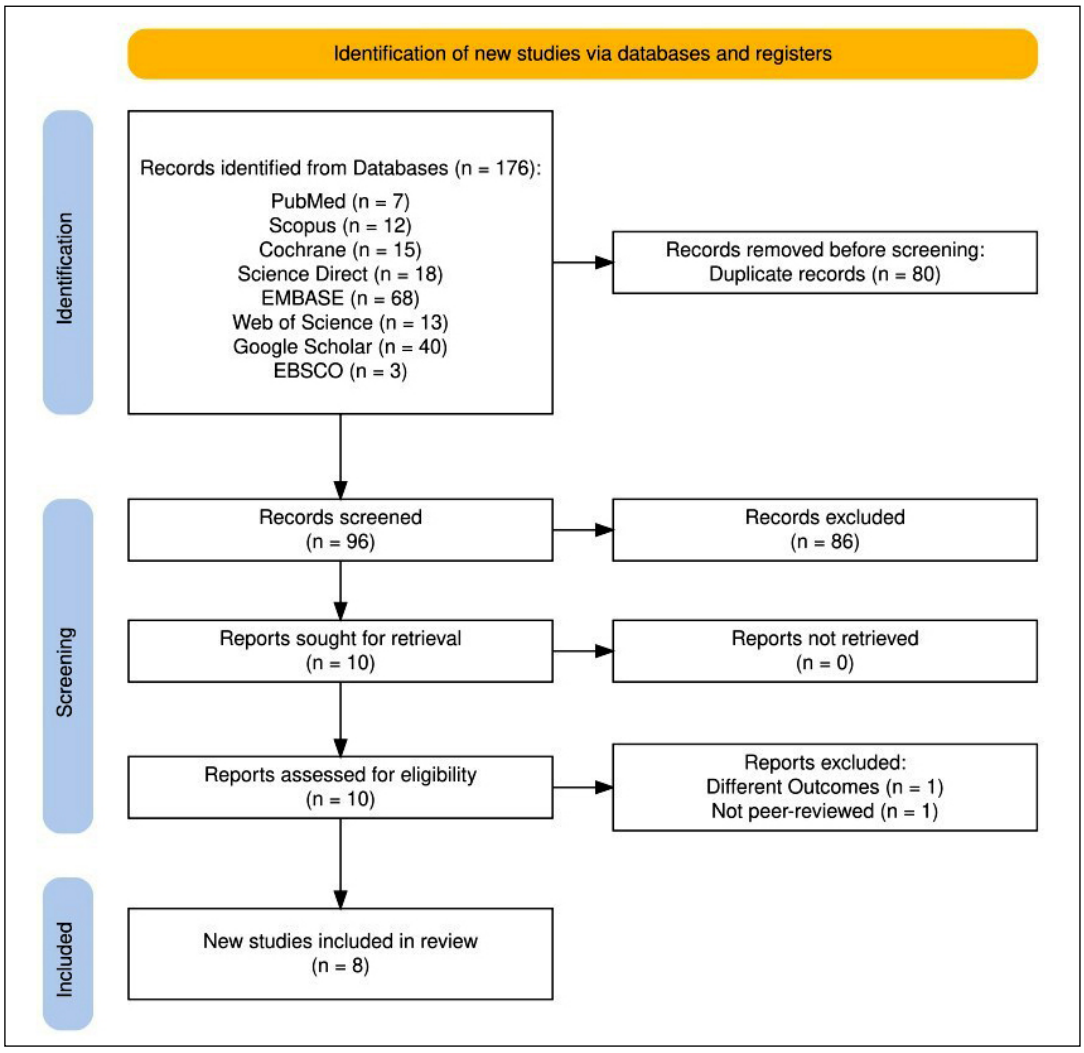


Figure 1. *PRISMA flow Diagram.*

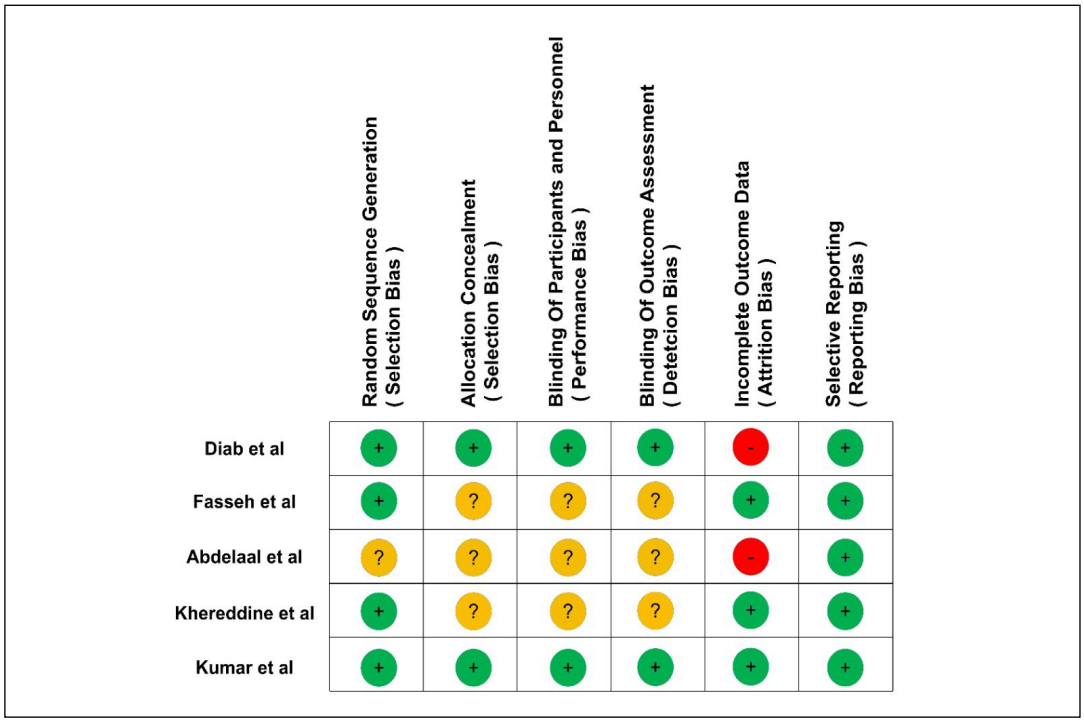
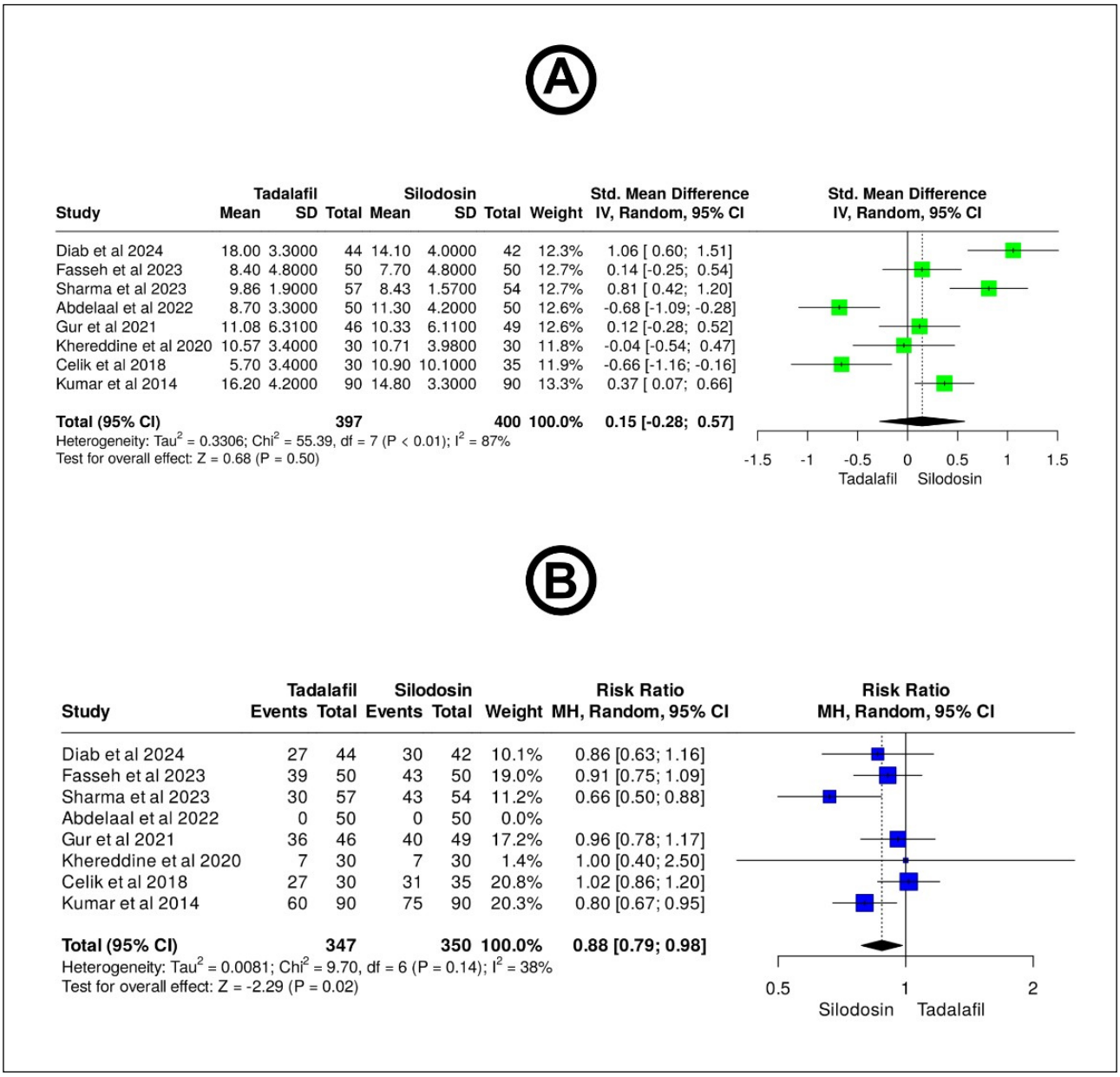


Figure 2. *Risk of Bias Assessment.*

Figure 3.
A: Stone expulsion time. B: Stone expulsion rate.



SET

Eight studies reported on SET comparing Tadalafil to Silodosin, as shown in Figure 3. The pooled analysis of these studies showed no statistically significant difference, with the overall *mean difference* (MD) = 0.15 (95% CI [-0.28, 0.57], p = 0.50). A random-effects model was applied due to significant heterogeneity (Chi-square p < 0.01, I^2 = 87%). We used sensitivity analyses but did not identify any study that significantly affected the pooled estimate, and we could not resolve the heterogeneity.

SER

Eight studies reported on stone expulsion rate (SER) comparing Tadalafil to Silodosin (17-24). The pooled analysis showed no significant difference between Tadalafil and Silodosin in the incidence of stone expulsion rate (RR = 0.92, 95% CI [0.80 to 1.05], p = 0.22), with heterogeneity (p = 0.01).

To resolve the heterogeneity, we conducted a sensitivity analysis in multiple scenarios, excluding one study in each scenario. Heterogeneity was best resolved by excluding the study of *Abdelaal et al.* (20) (p = 0.14, I-square = 38%). After removing Abdelaal et al. from the meta-analysis model, the overall RR favored Silodosin over Tadalafil (RR 0.88, 95% CI [0.79 to 0.98], p = 0.02), as shown in Figure 3.

Headache

Six studies reported headache as a side effect, as shown in Figure 4A. The pooled analysis showed no significant dif-

ference between Tadalafil and Silodosin in the incidence of headache (RR = 1.16, 95% CI [0.77 to 1.73], p = 0.48), with no heterogeneity.

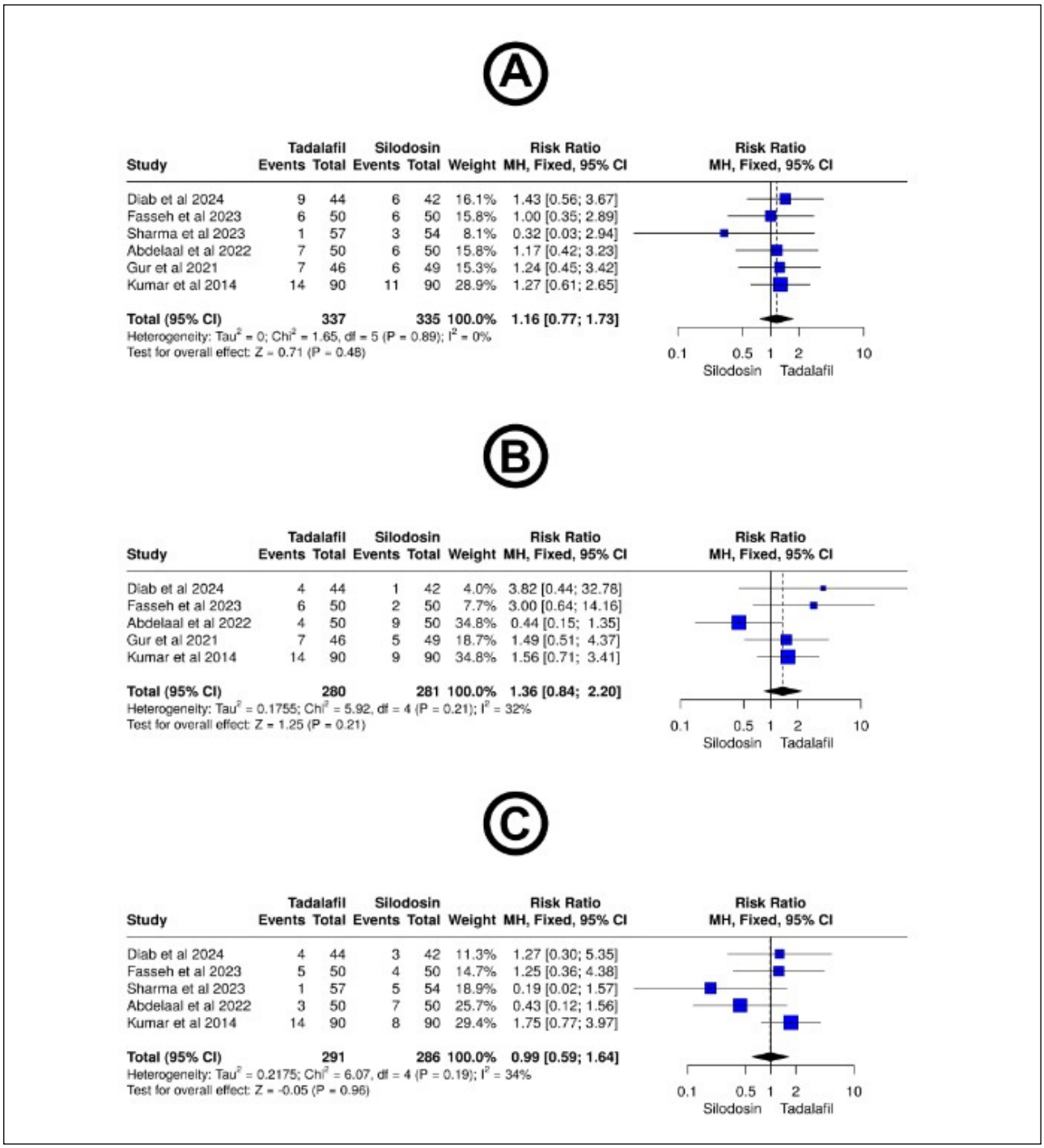
Backache

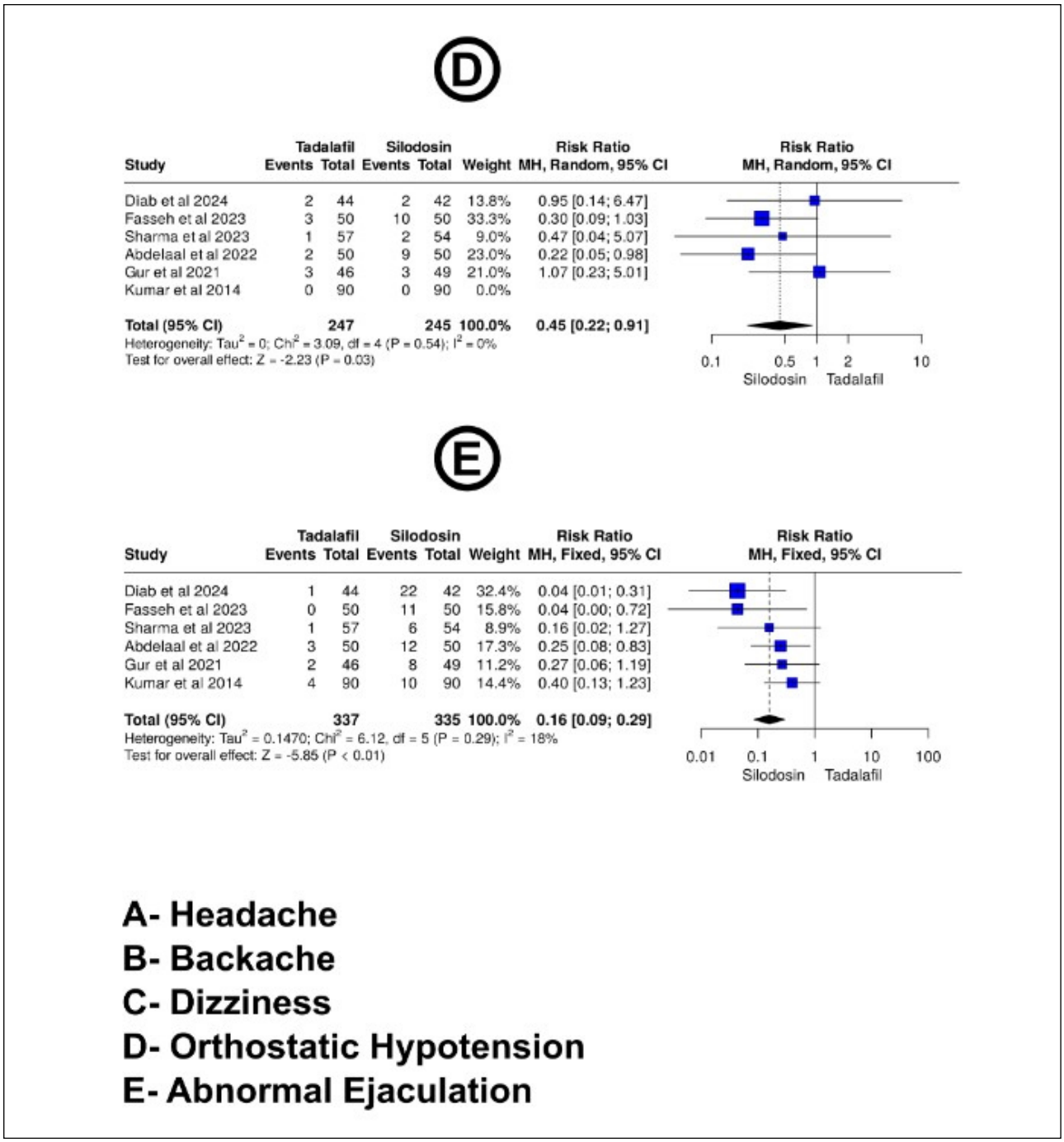
Five studies reported backache as a side effect, as shown in Figure 4B. The pooled RR was 1.36 (95% CI [0.84 to 2.20], p = 0.21), with no significant difference between the two groups and no heterogeneity.

Dizziness

Five studies reported dizziness as a side effect, as shown in Figure 4C. The pooled analysis indicated no significant difference in dizziness rates between Tadalafil and

Figure 4.
Adverse effects.
A- Headache. B: Backache. C: Dizziness. D: Orthostatic hypotension. E: Abnormal ejaculation.





Silodosin (RR = 0.99, 95% CI [0.59 to 1.64], p = 0.96), with no heterogeneity observed.

Orthostatic hypotension

Six studies reported on Orthostatic Hypotension comparing Tadalafil to Silodosin. The pooled analysis showed no significant difference between Tadalafil and Silodosin in the incidence of Orthostatic Hypotension (RR = 0.69, 95% CI [0.29 to 1.68], p = 0.42), with heterogeneity (p = 0.09). To resolve the heterogeneity, we conducted a sensitivity analysis in multiple scenarios, excluding one study in each scenario. Heterogeneity was best resolved by excluding the study of *Kumar et al.* (24) (p = 0.54, I-square = 0%). After removing *Kumar et al.* from the meta-analysis model, the overall RR depicts that Silodosin causes more Orthostatic hypotension than Tadalafil (RR 0.45, 95% CI [0.22 to 0.91], p = 0.03), as shown in Figure 4D.

Abnormal ejaculation

Six studies reported abnormal ejaculation as a side effect of treatment. As shown in Figure 4E the pooled analysis showed a significant difference between Tadalafil and Silodosin (RR = 0.16, 95% CI [0.09 to 0.29], p = 0.01), favoring Silodosin, with no heterogeneity.

Discussion

In 2006, Silodosin was first released in the Japanese market as the newest generation of alpha blockers as a promising treatment in voiding dysfunction (25).

Since 2010, there has been a new emerging debate about using Tadalafil and Silodosin as a MET in lower ureter stones. *Kumar et al.* (24) was the first to put both drugs in direct comparison with each other for MET of lower ureter stones through a double blind randomized control trial, showing that both drugs are effective with few and tolerable adverse effects. This led to further studies and clinical trials which demonstrated that they were comparable to other drugs used for MET (5).

The first and only meta-analysis comparing Tadalafil and Silodosin was delivered by *Ebrahimpour et al.* (7), with a total of five studies included in the Meta analysis. Since then several high-quality studies were published, allowing for a more robust evidence synthesis. Our meta-analysis adds evaluation of adverse events and solving of the heterogeneity which wasn't taken care of in the previous Meta-analysis. This broader approach provides a more comprehensive view of treatment effects beyond the scope of the previous analysis, enabling a more detailed comparison of treatment efficacy and adverse events.

To our knowledge, this is the most comprehensive Systematic review and Meta-analysis comparing Tadalafil and Silodosin. Pooled results of our study showed that Silodosin and Tadalafil had no significant difference on Stone Expulsion Rate, however after solving high heterogeneity by deleting the study of *Abdelaal et al.* (20) it was shown a statistically significant difference between Silodosin and Tadalafil favoring Silodosin.

We believe that *Abdelaal et al.* study (20) was a poorly controlled clinical trial, with relatively high risk of bias. The study didn't mention the type of randomization and modality of allocation, and the materials and method section was brief, blurry, with weak writing skills. *Abdelaal et al.* was the only study among all the eight studies that pointed towards the use of Tadalafil (5 mg) as a MET with a high significant difference between it and the Silodosin, which raised a lot of concern about the methodology of the study.

Although Silodosin and Tadalafil had no significant difference in terms of SET, Silodosin showed positive trends towards SET without reaching significance level. Results of the adverse effects showed that patients on Silodosin had a relatively higher chance for orthostatic hypotension and abnormal ejaculation (e.g. loss of seminal emission) than patients on Tadalafil as shown by the significant difference between the two drugs. The mechanism of orthostatic hypotension is due to the natural effect of Silodosin on alpha receptors which are extensively located on blood vessels (particularly alpha-1 receptors) (26). Abnormal ejaculation caused by Silodosin is related to decreased number of bulbocavernous floor muscle contractions, thus decreasing semen discharge (27).

Kumar et al. (24) and *Sharma et al.* (19) were the only two studies that used oral tablets with 10 mg Tadalafil, unlike the rest of the studies, however no statistical difference was observed even after the administration of 10 mg Tadalafil. Furthermore Tadalafil group in *Kumar et al.* (24) was associated with a higher incidence of adverse events including hypotension and abnormal ejaculation witch raise concerns and question about dose related adverse effects of Tadalafil as a MET.

Huang et al. (28) demonstrated that patients with distal ureteric stones who were treated with Silodosin had an expulsion rate of 83.5% and a mean expulsion time of 11 days. This was significantly better than the results for Tamsulosin, which had an expulsion rate of 66.9% and a mean expulsion time of 14 days, along with a notable reduction in pain episodes.

Combination of Silodosin and Tadalafil have showed positive results on SET and SER when used as a Medical Expulsive Therapy, with variations between the studies about how tolerated is the combination by the patients (29).

Strength and limitations

A major strength of this study is the exhaustive inclusion of all available clinical trials that directly compare Tadalafil and Silodosin treatment for distal ureter stones below 10 mm. Our team conducted an extensive search across all major databases to ensure a comprehensive dataset; moreover, the study solved the heterogeneity that came across the results using random effect model and sensitivity analysis; finally, an extensive analysis of all the possible adverse effects of both drugs was done.

Despite adhering to PRISMA guidelines, our study has limitations that must be acknowledged. First, the heterogeneity found upon analysis of Stone Expulsion Time couldn't be solved by any method: Random effect model; Sensitivity analysis and Selective regression were all useless.

Second, the high risk of bias in some studies should be taken into account when interpreting their results. Further high-quality RCTs with larger sample sizes and longer follow-up periods are needed to further support our results.

Conclusions

Silodosin has shown better results in terms of stone expulsion rate, together with positive trends towards stone expulsion time making it a valued drug than Tadalafil as a MET despite the fact that no significant differences were observed. However, assessment of adverse effects while giving the patients Silodosin should be taken in account as, especially, orthostatic hypotension and abnormal ejaculation. Further high-quality RCTs with larger sample sizes and longer follow-up periods are needed to further support our results.

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Declarations

Registration: *Study was registered on Prospero carrying the ID number (CRD42024597302).*

Availability of data and material: *The datasets used and/or analyzed during the current study are available upon reasonable request from the corresponding author (Yousif A.Hanafi).*

Competing interests: *The authors declare that there is no conflict of interest regarding the publication of this paper. All research was conducted in accordance with ethical standards and without any financial or personal relationships that could influence or affect the results.*

Funding: *None to be reported.*

Authors' contributions: *Conception: MS and YH; Design: MS; Data acquisition: MS,YH and KM; Data analysis: MS, YH, OA, ZA and MA; Interpretation of Data: HG, BH, RA, MA and OA; Drafting of manuscript: BH, YH, KM, HG and MS; Critical revision of the manuscript: BH, MS, HG and YH. All authors confirm that have approved the submitted version of the paper and have agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.*

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