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REVIEW

Is the vacuum erectile device suitable for treating erectile dysfunction? A systematic review and meta-analysis exploring the evidence gap

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Summary ***Introduction: VED is a handheld pump that creates negative pressure around the penis to draw blood into the corpora cavernosa. Although included in guidelines as a noninvasive option, its uptake is limited by fragmented evidence. Current Grade C recommendations are largely based on post-prostatectomy studies, and no systematic review/meta-analysis has evaluated VED across other ED etiologies (diabetic, cardiovascular, idiopathic) or compared it head-to-head with pharmacotherapy using the IIEF.***
Methods: We searched PubMed, Science Direct, and Cochrane Library using relevant keywords to identify studies assessing VED's effects on erectile dysfunction patients. The primary outcome we assessed in this systematic review was erectile function based on the International Index of Erectile Function (IIEF). Study quality was assessed using the Revised Cochrane Risk of Bias tool (RoB2) for Randomized Controlled Trial (RCT) study and using ROBINS-I for non-RCT study. Meta analyses were conducted using Review Manager 5.4.
Results: The meta-analysis results of this study showed that when VED was used as a single therapeutic modality compared with Phosphodiesterase-5 (PDE5) inhibitors (PDE5Is), there was no significant difference (p = 0.77). However, when compared with the placebo group (no intervention), VED provided significantly better outcomes [MD: 4.44 (95% CI: 3.04-5.84) p < 0.001). Similarly, when VED was combined with PDE5i, its effectiveness was significantly better than PDE5i therapy alone [MD: 4.19 (95% CI: 0.81-7.57; p < 0.001)]. In terms of safety, VED is also relatively safe and has mild and reversible side effects.
Conclusions: VED is effective as a therapy either alone or as an adjunct to PDE5i therapy in patients with erectile dysfunction.

KEY WORDS: Erectile dysfunction; Meta-analysis; Vacuum erectile device.

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INTRODUCTION

Globally, *erectile dysfunction* (ED) affects hundreds of millions of men with its prevalence projected to reach 322 million by 2025, severely impairing quality of life and psychosocial well-being (1). It is a common disorder, especially in middle-aged and older men, with prevalence increasing with age and often accompanying chronic conditions such as diabetes, hypertension and cardiovascular disease (2). Current first-line therapies for ED, including Phosphodiesterase-5 inhibitors (PDE5i) and intracavernosal injections, demonstrate substantial discontinuation rates in clinical practice due to various factors including insufficient therapeutic response, adverse effects, and cardiovascular contraindications (3, 4). In such cases (or in patients unwilling or unable to take medication), non-drug therapies are used.

A *vacuum erection device* (VED) is a hand-held pump that creates negative pressure around the penis to draw blood into the corpora cavernosa, usually followed by an elastic constriction band at the base to maintain the erection (1). Despite guideline recognition of *vacuum erection devices* (VEDs) as a non-invasive alternative, their clinical adoption remains limited by fragmented evidence. VEDs hold Grade C recommendations in major guideline, primarily based on studies in post-prostatectomy populations (5). No systematic review has evaluated VED efficacy across broader ED etiologies (such as: diabetes mellitus, cardiovascular, and idiopathic), in which erectile function outcomes are evaluated using the gold standard questionnaire, the IIEF score.

Existing systematic reviews of VEDs exhibit important limitations: which predominantly only focus on post-radical prostatectomy cohorts and therefore do not capture the full spectrum of ED etiologies (5, 6).

Furthermore, few reviews provide rigorous comparator meta-analyses using standardized IIEF endpoints. To address these evidence gaps, this review evaluated whether VED therapy (used alone or in combination with standard treatments) yields greater improvement in IIEF scores compared with pharmacotherapy, other standard interventions, or no intervention across heterogeneous ED populations.

Synthesizing high-grade evidence on this question is essential for optimizing rehabilitation protocols and guiding clinical decision-making for patients who are refractory to or unsuitable for first-line pharmacotherapy.

Materials and methods

Protocol

Eligibility criteria

The study criteria that were included in this systematic review are as follows:

- Participants/population
  Patients with ED or patients who will undergo procedures that risk reducing ED
- Intervention(s)
  VED either alone or in combination with other standard therapies
- Comparator(s)/control
  Control group included other standard therapies or no intervention (placebo)
- Outcome
  ED based on International IIEF.

Literature search

In this systematic review, a literature search was conducted on May 28th 2024 from various databases, PubMed, Science Direct, and Cochrane Library with limitation by English language. All of these searches were conducted on Google Chrome web browser. The search was carried out using the following keywords: [(Vacuum Erectile Device) OR (Vacuum Device) OR (Vacuum Constriction Device) OR (Penis pump) OR (Erectile dysfunction pump) OR (Vacuum erection assistance devices) OR (VED) AND (Erectile dysfunction) OR (Impotence)].

Selection process

The study selection process was carried out by two reviewers independently using a web-based application (*rayyan.ai*). One reviewer (AT) will initially screen records for inclusion based on predetermined inclusion criteria. This will be done by screening titles and abstracts, followed by full-text assessment for eligibility. A second reviewer (MA) will then check decisions independently. Disagreements will be discussed to reach a consensus. Furthermore, one additional reviewers with relevant expertise will be called in. The results of the screening of studies will be reported using *Preferred Reporting Items for Systematic Reviews and Meta-Analysis* (PRISMA).

Data collection

Data will be extracted by one reviewer (AT), including information on study design and methodology, participant characteristics, VED intervention characteristics [e.g. dose, duration of intervention, intervention status (single or combination)], and outcomes of the study. A second and third reviewer (MA & AA) will check the extracted data. Differences of opinion will be discussed to reach consensus. Next, one additional reviewer with relevant expertise will be called. Data will be recorded in an Excel spreadsheet. If in the included studies there are incomplete data, the reviewer (AT) will contact the corresponding author of the study; if the corresponding author does not respond, the study is then excluded with the reviewer's agreement.

Risk of bias (quality) assessment

The quality assessment of included studies was conducted using two methods depending on the study type. RCT studies were assessed using the revised Cochrane risk of bias tool (RoB2), while non-RCT studies were assessed using the *Risk of Bias in Non-randomized Studies of Interventions* (ROBINS-I). The quality assessment of each study was conducted by two independent reviewers. Any discrepancies in the assessments were discussed together. If unresolved, a third reviewer assisted in the decision.

Statistical analysis

The meta-analysis will be conducted to compare intervention group with control group. The data used in this study is continuous data so we entered the mean IIEF change (Post intervention value-Pre intervention value) in the meta-analysis along with its standard deviation to calculate the overall mean difference with 95% *confidence intervals* (CI). We will use fixed-effects models for all meta-analyses. However, if the heterogeneity value (I square) is high > 50%, it will be converted to a random-effects model. We will perform subgroup analysis based on the treatment duration (≤ 6 months and > 6 months).

Publication bias

Publication bias is evaluated subjectively by looking at the funnel plot. Publication bias is high if the distribution of studies in the funnel plot is not symmetrical. Conversely, if the study distribution is evenly distributed and symmetrical in the funnel plot, it can be said that publication bias is low.

Results

Literature search and result of screening

After searching for studies from various databases using appropriate keywords, we found a total of 814 studies. Before screening, 17 duplicate studies were excluded, leaving 797 studies that underwent title and abstract screening. A total of 746 studies were excluded because they did not meet the eligibility criteria. Furthermore, 51 studies were further assessed in full-text and 32 studies were excluded because they did not meet the criteria, leaving 19 studies included in this systematic review. (Figure 1).

Characteristics of the included studies

A total of 19 studies were included in this systematic review, consisting of 9 RCTs (7-15) and 10 non-RCTs. (7, 16-23). ED was diagnosed in all studies using the IIEF questionnaire. The use of VEDs varied widely among the included studies. Six studies assessed the effects of VED therapy as penile rehabilitation after radical prostatectomy, six others assessed VED therapy in patients with general ED, three studies assessed the effects of VED therapy in patients with spinal cord injury-induced ED, and one study each assessed the effects of VED therapy in patients with DMED, penile rehabilitation after PFUI, adjuvant therapy in patients with psychogenic ED, and therapy before penile implantation. All studies reported self-reported primary outcomes using the IIEF questionnaire. Full details of the

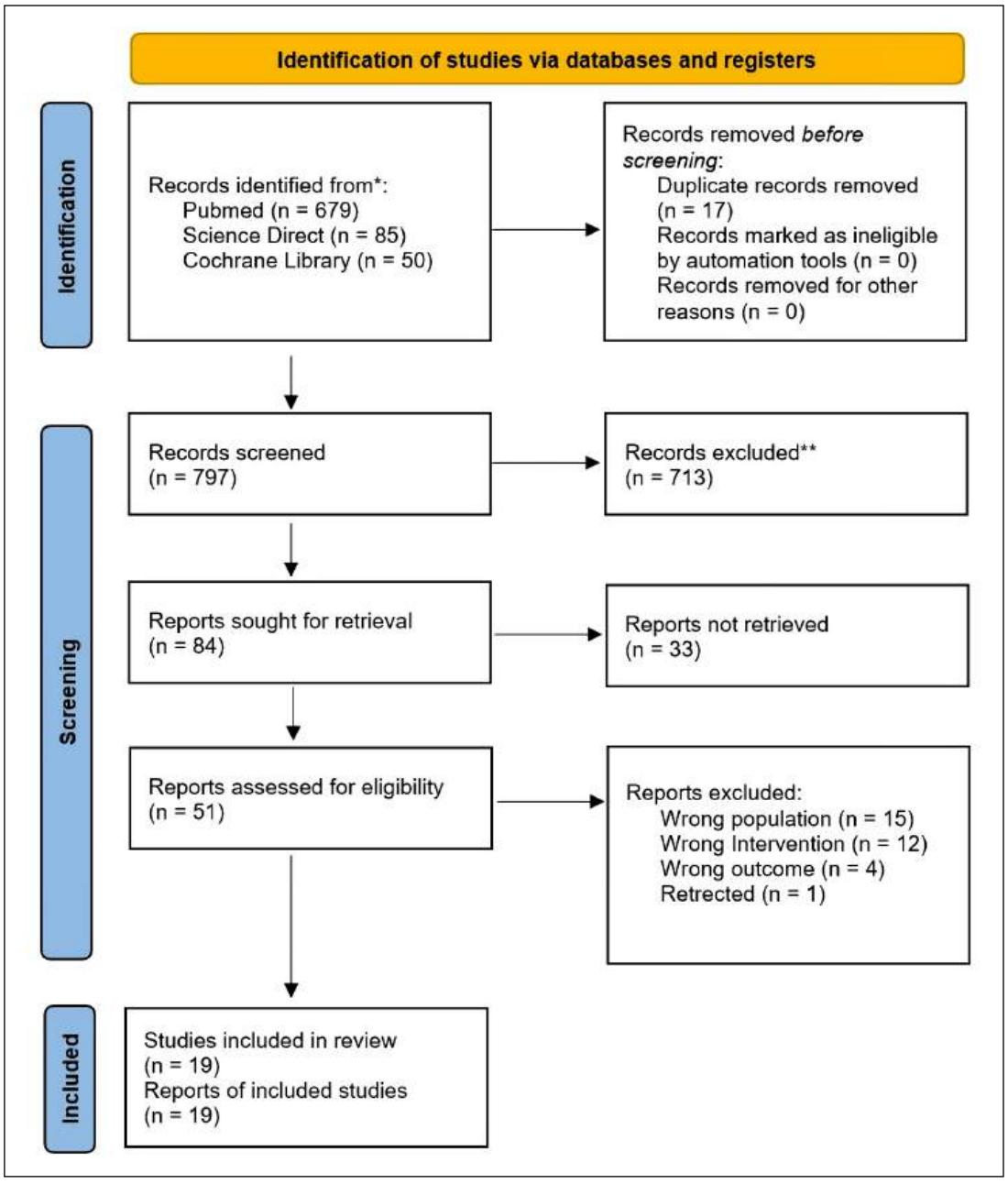


Figure 1. *Preferred Reporting Items for Systematic Review and Meta-Analyses flow chart.*

characteristics of the included studies are presented in Table 1.

Quality assessment result

Quality assessment of included studies was carried out by two reviewers independently (AZT and RR) according to the Cochrane risk of bias tool (RoB 2) for RCT studies. In general, domain one (Bias arising from the randomization process), domain four (Bias in measurement of the outcome), and domain five (Bias in selection of the reported result) have a low risk for each study. In general, the process of randomizing samples, determining intervention groups, and assessing outcomes in all included studies was carried out well and had minimal risk of bias. In domain two (Bias due to deviations from intended intervention) There are two studies that fall into the high-risk category and two other studies that fell into the 'some concern' category. This is because the study provided self-intervention in the form of VED to patients without explaining any prior assistance or training. In domain three (Bias due to missing outcome data) there are two studies that fall into the "*High risk*" category because the number of participants lost to follow-up was > 10%. Overall, 4 of the included studies were in the "*Low risk*" of bias, 2 studies were in the "*Some concern*" category, and 3 studies were in the "*High risk*" of bias (Figure 2A).

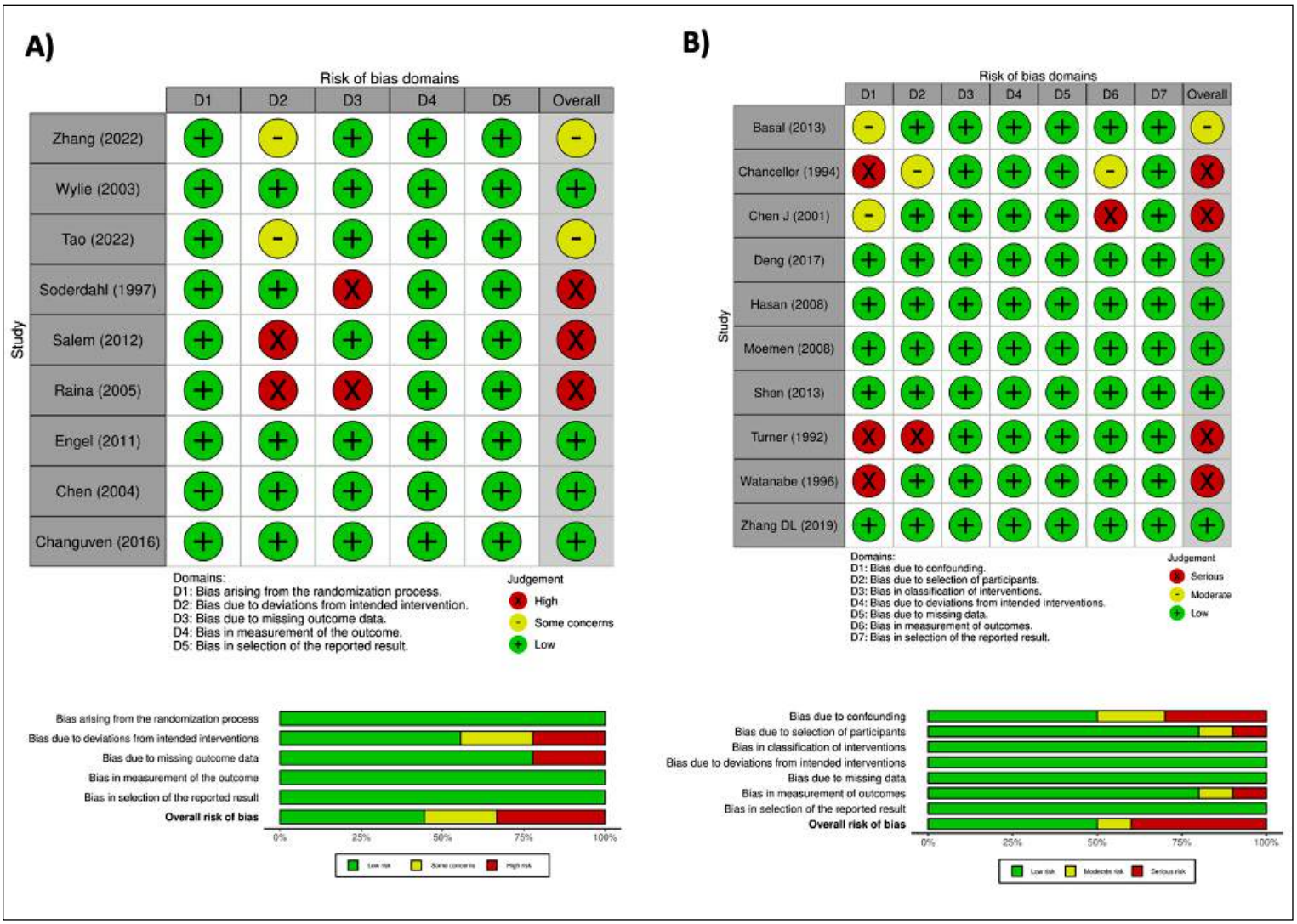
In non-RCT studies, quality assessment was performed using the ROBINS-I tool. The results showed that domains three (Bias in classification of interventions), domain four (Bias due to deviations from intended interventions), domain five (Bias due to missing data), and domain seven (Bias in selection of the reported result)

Table 1.
Characteristics of Included Studies.

No	Author	Country	Study design	Participants	Grouping	Total sample		Age (Mean, SD)		Durationn of intervention	Follow up time
						Intervention	Control	Intervention	Control		
1	*Zhang DL, 2019*	China	non-RCT	ED after primary posterior urethroplasty (PFUI)	1) Group 1: VED 10 min (twice/day) + Tadalafil 10 mg/day 2) Group 2: Tadalafil 10 mg/day	36	42	32.3 ± 7.1	33.9 ± 7.2	6 months	6 months
2	*Zhang M, 2022*	China	RCT	Patients with localized prostate cancer prior to surgery	1) Group T: Tadalafil 5 mg 2) Group V: VED 15 min (twice/day) 3) Group T + V: Combination 4) Group C: Control (No intervention)	1) (Group T): 25 2) (Group V): 25 3) (Group T+V): 25	25	1) Group T: 63.6 ± 4.5 2) Group V: 61.9 ± 6.6 3) Group T + V: 63.7 ± 7.4	67.2 ± 5.1	12 months	6 months and 12 months
3	*Wylie, 2003*	England	RCT	Psychogenic erectile disorder (ED)	1) Group 1: VED + Psychotherapy 2) Group 2: Psychotherapy only (40-50 minutes every 2 weeks)	25	20	N/A	N/A	6 weeks	6 weeks
4	*Watanabe, 1996*	US	non-RCT	ED due to SCI	1) Group 1: VED 2) Group 2: Penile injection 3) Group 3: VED + Penile injection 4) Group 4: Counseling only 5) Group 5: Penile prosthesis 6) Group 6: Topical nitroglycerin 7) Group 7: Other therapy	1) VED: 28 2) Pharmacological penile injection: 26 3) Combination: 5	7	N/A	N/A	Not specified	Not specified
5	*Turner, 1992*	US	non-RCT	General ED Patients	Group A: VED	36	42	58,7	54,4	12 months	12 months
6	*Tao, 2022*	China	RCT	Diabete mellitus-induced erectile dysfunction (DMED)	1) Group A: VED Intervention (15 min, daily) 2) Group B: Li-ESWT (Twice a week) (Control) 3) Group C: VED + Li-ESWT	1) Group A = 34 2) Group C = 33	33	1) Group A = 47.97 ± 5.69 2) Group C = 48.30 ± 3.49	46.70 ± 4.93	9 weeks	12 weeks
7	*Soderdahl, 1997*	US	RCT	Untreated Erectile Dysfunction	1) Group 1: VED 2) Group 2: Intracavernosal self-injection (ICI)	27	23	62.3 (38-84) years	62.3 (38-84) years	After 15 times use VED	24 months
8	*Shen, 2013*	China	non-RCT	Patients with PCa who under-went radical prostatectomy (RP)	1) Group 1: VED (5 min, twice) 2) Group 2: PDE-5i (Sildenafil 50 mg, daily) 3) Group 3: Combination	1) Group 1: 12 2) Group 2: 25 3) Group 3: 6	144	60.1 years	66.5 years	18 months	18 months
9	*Salem, 2012*	Egypt	RCT	Organic ED	1) Group A: VCD (twice/week) 2) Group B: ICI (twice/week) 3) Group C: Sildenafil (twice/week)	Group A: 54	1) Group B (ICI): 56 2) Group C (Sildenafil): 55	< 40 years	< 40 years	3 months	4 months
10	*Raina, 2005*	US	RCT	ED after RP	1) Group A: VCD Group (Daily, after catheter removal/2 weeks after surgery) 2) Group B: No Treatment	74	35	58.6(50-71) years	58.6 (50-71) years	9 months	9 months
11	*Moemen, 2007*	Egypt	non-RCT	ED due to SCI	1) Group A: Sildenafil 25-50 mg 2) Group B: ICI (Prostaglandin E1) 3) Group C: VCD	20	1) A = 20 2) B = 20	24-52 (34.90 ±7.75)	1) A = 28-52 (35.55 ± 6.35) 2) B = 24-48 (32.70 ± 6.67)	2 months	2 months
12	*Hassan, 2008*	Egypt	non-RCT	General ED Patients	1) Group A: Oral testosterone 120 mg/day 2) Group B: Sildenafil citrate 100 mg.day 3) Group C: ICI (Papaverine + Phentolamine + Prsotaglandin) 4) Group D: VCD 5) Group E: Penile prosthesis	Gr1 = 51 Gr2 = 156 Gr3 = 105 Gr4 = 32 Gr5 = 10	No control	Gr1 = 37.12 ± 15.2 Gr2 = 37.51 ± 7.15 Gr3 = 35.15 ± 5.12 Gr4 = 43.67 ± 7.13 Gr5 = 49.21 ± 8.12	N/A	12 months	12 months
13	*Engel, 2011*	US	RCT	Patients with prostate cancer (PCa) who underwent radical prostatectomy (RP)	1) Group 1: Tadalafil Alone (20 mg, three times per week) 2) Group 2: Tadalafil + VED (5 days/week, 10 minutes daily)	13	10	< 65 years	< 65 years	12 months	Pre-op, 1, 3, 6, 9, and 12 month
14	*Deng, 2017*	China	non-RCT (Prospective controlled trial)	Patients who were scheduled for TME	1) Group 1: No Intervention (Control) 2) Group 2: Sildenafil 25 mg/day 3) Group 3: Sildenafil 25 mg/day + VED 10-15 minute/day	1) Group S = 29 2) Group S + VED = 17	44	1) Group S = 42.5 ± 6.5 2) Group S + VED = 37.0 ± 10	50.1 ± 9.4	3 months	3, 6, and 12 months after surgery
15	*Chen, 2004*	Israel	RCT	General ED Patients	1) Group 1: Sildenafil 25, 50, or 100 mg (45-60 minutes before sexual activity) 2) Group 2: VED 3) Group 3: Combination	1) VED = 51 2) VED + Sildenafil = 41	35	1) VED = 64 (35-82) years 2) VED + Sildenafil = 58 (41-72) years	67 (43-85) years	2 months	2 months
16	*Chen, 2001*	Israel US	non-RCT (Crossover trials)	General ED Patients	1) Group 1: Preffered using VED 2) Group 2: Preffered using Sildenafil	12	24	59 years (35-77)	59 years (35-77)	6 months	6 months
17	*Chancellor, 1994*	Qatar	non-RCT	ED due to SCI	1) Group A: 1 ml of a 2% Minoxidil topical 2) Group B: VCD 3) Group C: 10 mg intracorporeal papaverine injection	18	N/A	15-65 years (Median age 29)	N/A	Same time (Only to assess erectile response)	Same Time
18	*Changuven, 2016*	US	RCT	Severe ED seeking PP insertion	1) Group A: VED Intervention (10-15 min, daily) 2) Group B: non-VED	25	26	56.12 (± 10.59) years	54.19 (± 12.35) years	1 month before surgery	Unspecified
19	*Basal, 2013*		Retrospectively uncontrolled study	Patients with PCa who underwent RP	N/A	1) Group 1 = 48 2) Group 2 = 48 3) Group 3 = 107	N/A	1) Group 1 = 61.92 ± 6.59 2) Group 2 = 58.56 ± 7.30 3) Group 3 = 58.77. ± 7.43	N/A	Until 3 years after surgery	Unspecified

ED: Erectile Dysfunction; ESWT: Extracorporeal Shock Wave Therapy; RCT: Randomized Controlled Trial; PP: Penile Prosthesis; PCa: Prostate Cancer; RP: Radical Prostectomy; VCD: Vacuum constriction device; SCI: Spindal Cord Injury; TME: Total Mesorectal Excision); US (United States).

Figure 2.
Graph and summary of risk of bias of included studies. A) Randomized controlled trials (RCT) studies; B) Non-RCT.



showed a "*Low risk*" result for all studies. In domain one (Bias due to confounding), three studies were reported as "*Serious risk*" and two studies as "*Moderate risk*" This was because the characteristics and baseline data were not reported in the serious risk studies, while studies with moderate risk did not report some of the baseline characteristics or baseline values before the intervention. In domain two (Bias due to participant selection), one study was reported as "*Serious risk*" because it did not explain the participant selection method or sample origin, while one study was reported as "*Moderate risk*" because it only mentioned the sample origin but did not explain how it was recruited. In domain six (Bias in the measurement of outcomes), one study was reported as "*Serious risk*" and one study was reported as "*Moderate risk*" because the outcome measurement method was not reported.

Overall, 5 of the included studies were in the "*Low risk*" of bias category, 4 studies were in the "*High risk*" of bias category, and 1 study was in the "*Some concern*" category (Figure 2A).

Statistical test results (meta-analysis)

• VED *vs* PDE5i

We conducted a meta-analysis including four studies to assess the difference in effectiveness between VED therapy alone and PDE5i.

The meta-analysis results showed no significant difference in erectile function outcomes between patients given VED therapy as a single treatment compared with PDE5i with an overall mean difference of 0.52 (95% CI: -2.98-4.03; $p = 0.77$; $I^2 = 80\%$).

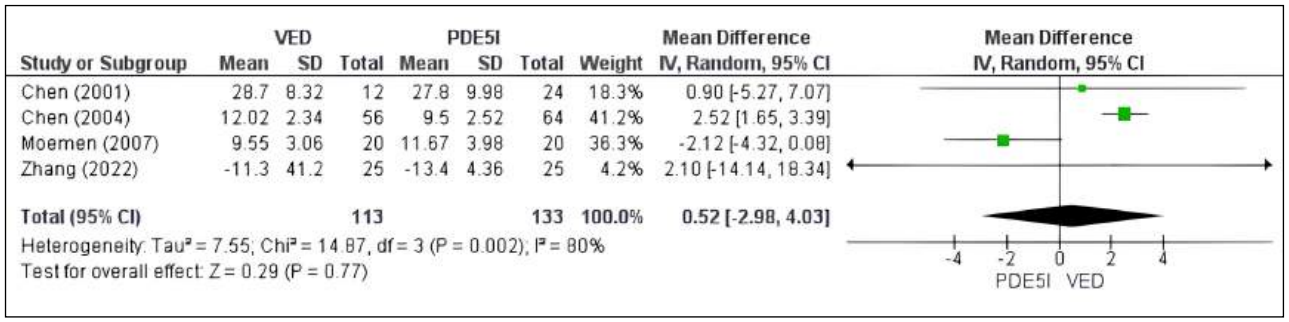
This indicates that VED therapy as a single modality is equivalent in effectiveness to PDE5i (Figure 3).

• VED Alone *vs* No Intervention

We conducted a meta-analysis by including two studies. The meta-analysis results showed a significant difference in erectile function outcomes between patients receiving VED therapy as a single treatment compared to patients not receiving any treatment for ED.

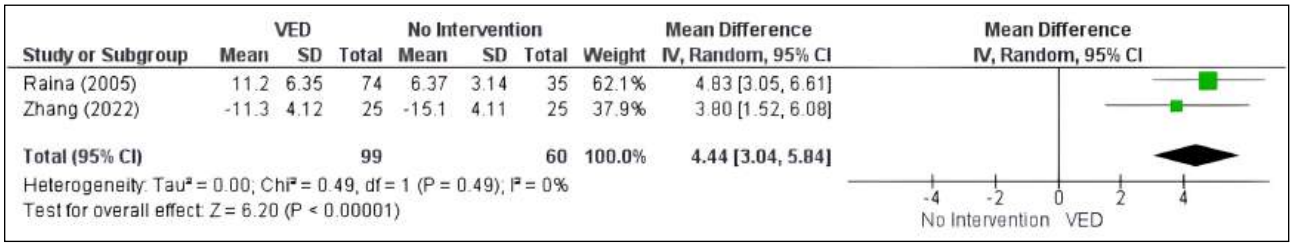
The results showed superiority in VED with an overall mean difference of 4.44 (95% CI: -3.04-5.84, $p < 0.001$, $I^2 = 0\%$).

Figure 3.
Meta-analysis of VED vs PDE5i.



This suggests that VED therapy as a single modality is effective in improving erectile function (Figure 4).

Figure 4.
Meta-analysis of VED Alone vs No Intervention.



• VED + PDE5i *vs* PDE5i alone

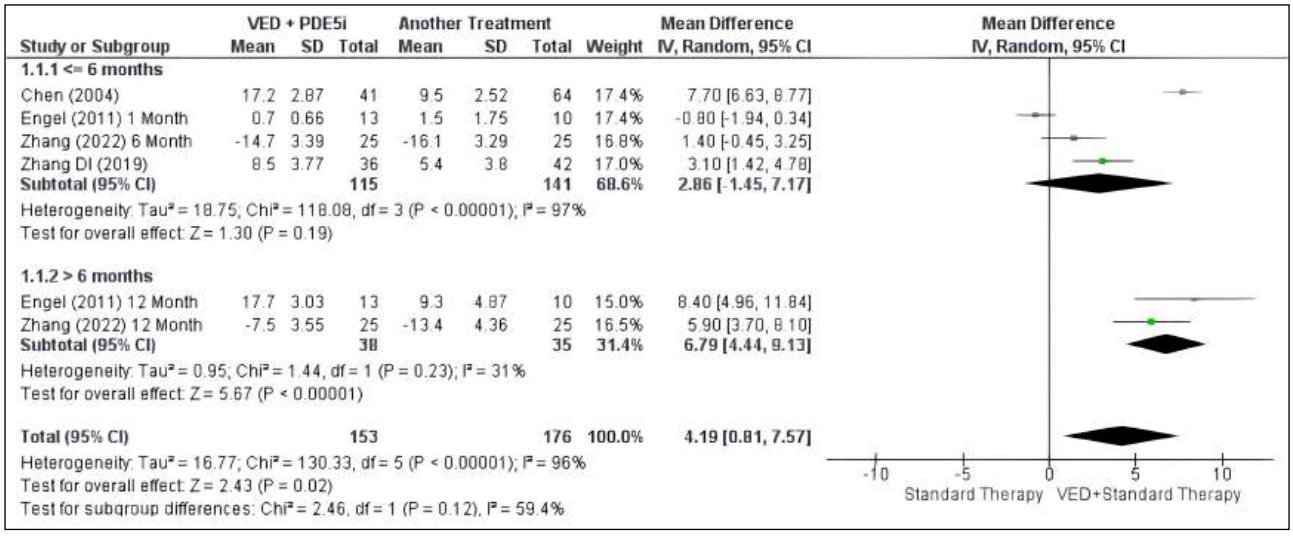
We conducted a meta-analysis including four studies to assess the difference in effectiveness between VED therapy combined with PDE5i and PDE5i alone. Two of the four included studies had two consecutive data sets with different timelines.

The meta-analysis results showed a difference in outcomes, with significantly better erectile function in patients treated with VED in combination with PDE5i compared to PDE5i alone, with an overall mean difference of 4.19 (95% CI: 0.81-7.57; p = 0.02; I^2 = 96%). Furthermore, subgroup analysis results showed that combination VED therapy given for more than 6 months provided better outcomes, although there was no significant difference compared to interventions given for less than 6 months (p = 0.12) (Figure 5).

Adverse events of VED

One study out of 9 studies specifically evaluated the adverse events that occurred during the usage of *Vacuum Erectile Device* (VED) therapy. *Chen et al. (2001)*, in a non-RCT study with 36 total ED patients with various aetiolo-

Figure 5.
Meta-analysis of VED Combination vs PDE5i inhibitor.



gies, reported that VED has a relatively low incidence of side effects, with the most frequent being penile numbness, bruising, and ejaculatory dysfunction. In addition, VED is also contraindicated for ED patients with bleeding disorder, anatomical penile deformities, or unexplained priapism. Of the 36 patients observed, side effects included pain in 3 patients, hematoma in 2 patients, numbness in 1 patient, and maceration in 1 patient. *Chen et al.* explained that none of the patients withdrew from the study due to these side effects (22).

Along with these findings, studies by *Raina et al.* (12) and *Zhang et al.* (24) also explained that the main reasons patients discontinued the VED therapy in most cases were adverse effects associated with the constriction ring, such as bruising and petechiae (5%), numbness (5%), and pain (10%). These findings indicate that VED therapy may cause mild and transient side effects, but it is generally well tolerated and did not lead to treatment discontinuation in the majority patients (12, 24).

Publication Bias

Publication bias was assessed subjectively using a funnel plot. A meta-analysis comparing VED monotherapy versus other therapies found a symmetrical distribution of studies, indicating a low risk of publication bias (***Supplementary Figure 1***). Meanwhile, a meta-analysis comparing VED monotherapy versus placebo also showed a symmetrical distribution, indicating a low risk of publication bias (***Supplementary Figure 2***).

Furthermore, a meta-analysis comparing VED combinations versus standard therapy also showed a symmetrical distribution, indicating a low risk of publication bias (***Supplementary Figure 3***).

Discussion

The results of this current meta-analysis showed that VED combined with PDE5i is significantly more effective to better erectile function in ED patients, compared to PDE5i alone. Meanwhile, the effect of VED therapy as monotherapy shows satisfactory results in patients with ED but with limited clinical evidence.

Previous studies have explored the potential of VED therapy but were limited by sample size and study design. For example, Ma et al. demonstrated that two consecutive VED therapy 5 minutes treatment protocols were optimal to increase the smooth muscle: collagen ratio, upregulate of endothelial *Nitric Oxide* (NO) synthase, and reduce hypoxia-related and fibrotic markers. However, the study's limitations include use of an animal model and small sample size (25).

In another study, *Zhang et al.* conducted an RCT study on scheduled PDE5i and VED for ED patients after nerve sparing prostatectomy; they found that tadalafil 5 mg once a day combined with VED can help improve IIEF5 score in *nerve-sparing radical prostatectomy* (ndRP) patients after 6 and 12 month therapy (7). Nevertheless, their study was constrained by a small sample size, focus on treatment of the primary disease rather than ED itself, and low enrolment due to extremely minimal sexual demand of elderly female partners.

Compared to these previous studies, our meta-analysis has a larger and more homogenous population, with a total of 732 human participants in 9 RCTs. Broader representation could increase the level of evidence on the topic.

Effect on sexual function of a VED post-prostatectomy. VED uses the negative pressure produced by the mechanical device to induce penile tumescence by passively increasing blood perfusion in the penile corpus cavernosum. VED treatment can increase arterial and venous blood in the corpus cavernosum simultaneously, mainly increasing arterial blood perfusion and resembling the physiology of spontaneous nocturnal erection. Later it can improve the hypoxia of corpus cavernosum (9, 25-27).

VED is primarily indicated for patients with organic ED and has been reported to achieve a high success rate with minimal side effects. Early initiation of VED therapy may facilitate earlier sexual activity, improve both patient and partner satisfaction, preserve penile length, and potentially accelerate the return of spontaneous erections (12). In addition, is considered as a simple, user friendly, and cost effective device compared to other treatment modalities (22).

In this systematic review, we conducted a meta-analysis which include 4 studies that compared patients treated with VED therapy alone with PDE5i, who were followed up for several weeks to months. Difference is not significant, with overall mean difference of 0.52 (95% CI: -2.98-4.03; p = 0.77) and substantial heterogeneity (I^2 = 80%). Although some individual studies suggested potential benefit of VED, most findings of the studies were not statistically significant. For example, *Chen et al.* (22) reported no improvement in sexual desire or patient satisfaction after 6 months of VED compared with sildenafil. Similarly, *Moemen et al.* (19) in a 2-month follow-up and *Zhang et al.* (7) in a 6- and 12-month follow-up found no significant differences when comparing VED with PDE5i and *Tao et al.* (9) also observed no significant advantage of VED over ESWT after 4 and 8 weeks. On the other hand, *Chen et al.* (14) showed that neither sildenafil nor VED improve sexual desire and patient satisfaction, but the combination of both significantly enhanced all domains of the IIEF and improved patient satisfaction according to the *global assessment question* (GAQ). This finding suggests that improvement in erectile function alone may not be sufficient to enhance overall patient satisfaction (14).

The heterogeneity in this analysis is high, which may be attributed to differences in study design, duration of therapy, and patient population.

Our systematic review also compared the effectiveness of VED treatment alone versus no intervention, and the pooled analysis showed significant difference. However, more consistent and larger-scale trials are needed to confirm the role of VED compared to no intervention.

This systematic review also included 4 studies that compared the effectiveness of VED + PDE5i combination with PDE5i alone, showing that the use of VED as an adjuvant therapy significantly improves erectile function, especially when given > 6 months.

The previous clinical research on the use of PDE5i, such as 5 mg tadalafil daily in ED after nsRP patient, have shown improvement in patients' satisfaction of the penis conges-

tion in the morning, however, after 12 month follow up, without any significant assisted erectile function after a 6 weeks withdrawal period. Moreover, PDE5i monotherapy is not effective in preventing the penile shortening, a common complication occurring 4-8 months after radical prostatectomy. The gradual shortening effect can affect the patients standing urination ability and causing a serious psychological burden. In contrast, VED can prevent this condition by improving the peak flow velocity and vascular diameter of the cavernous arteries of patient with organic ED, which will prevent the penis corpus cavernous fibrosis. However, the effect of fully erection function recovery with VED only is not always significant. Therefore, combining PDE5i and VED could act synergistically to promote the erection function and prevent the anatomical damage, for a better short-long prognosis in ED patients (7). This additive effect is supported by *Engel et al.* (13), who found that combination therapy not only improved sexual function earlier in the recovery process but also enhanced patient compliance, confidence, and satisfaction, without dropout due to lack of efficacy. These findings suggest that dual therapy may provide comprehensive rehabilitation benefits by addressing both functional and structural aspects of ED (13).

Despite the significant improvement in erectile function and the high rates of partner satisfaction with VED therapy in patients with ED, studies have reported discontinuation rates of approximately 10-56% within one year of VED use. The main reasons for dropout include side effects such as bruising and petechiae (5%), numbness (5%), and pain (10%) (24). Some patients complain that the combination therapy of VED with other modalities (sildenafil) is cumbersome and chose to discontinue this treatment modality. Other reported contraindications to this treatment modality, including bleeding disorders, anatomical deformation of the penis, and priapism of unclear aetiology.

Finally, we acknowledge that our study has several shortcomings. The included studies consisted of non-RCTs, which reduces the quality of the evidence base. Furthermore, there is a high degree of heterogeneity of the meta-analysis due to differences in the doses, durations, and types of VEDs used.

Therefore, we recommend conducting larger studies with similar doses, durations, and types of VEDs to assess the adjuvant effects of VED therapy in patients with ED.

Conclusions

VED is effective when used alone and there is no significant difference in effectiveness between VED and PDE5i. However, when VED is combined with PDE5i, it provides significantly better outcomes compared to PDE5i therapy alone, especially when administered for > 6 months. While acknowledging the need for further research, results of this systematic review meta-analysis suggest that VED as an adjunctive therapy may provide additional benefit for men with ED.

Declarations

Ethical approval and consent for participate: *Not applicable.*

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	AR	ATF	MAG	AZT	RR	MF
Concepts		√	√			
Design	√	√	√	√	√	
Definition of intellectual content	√	√				
Literature search		√	√	√	√	
Clinical studies	√	√				√
Experimental studies						√
Data acquisition		√	√	√	√	√
Data analysis		√	√	√	√	
Statistical analysis		√	√	√	√	
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