How to Cite:

Ganesan, D., Prathap, L., Ling, L. Z., ChyeWah, Y., Suganthirababu, P., Pandian, S., & Ramalingam, V. (2022). Efficacy of vaginal weights in pelvic floor dysfunction: A systematic review and meta-analysis. *International Journal of Health Sciences*, 6(S3), 882–899. https://doi.org/10.53730/ijhs.v6nS3.5324

Efficacy of Vaginal Weights in Pelvic Floor Dysfunction: A Systematic Review and Meta-Analysis

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> **Abstract**---Pelvic floor dysfunction (PFD) affects women's quality of life because the pelvic floor muscles are unable to contract and relax properly. Kegel exercise is the first line of treatment for PFD, while vaginal cones with weights have recently been used for pelvic floor

International Journal of Health Sciences ISSN 2550-6978 E-ISSN 2550-696X © 2022.

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Manuscript submitted: 18 Nov 2021, Manuscript revised: 09 Feb 2022, Accepted for publication: 27 March 2022 882

strengthening. When compared to alternative treatments, various studies have evaluated the effectiveness of vaginal weights or cones in treating PFD. However, there are controversial conclusions reached when the effectiveness of vaginal weights is compared in various ways. The purpose of this study was determine the effectiveness of vaginal weights compared with other interventions in reducing the symptoms of PFD. Using various databases, an extensive literature search was conducted, and a randomised control trial examining the usefulness of vaginal weights in PFD was identified. PRISMA guidelines were used to synthesize the data. The risk of bias tools were used to assess the quality of the selected studies. Results suggest that vaginal cones are effective in treating PFD. However, when it was compared with other treatment modalities, no significant differences were found. Hence, the results are equivocal and cannot be generalized. Vaginal weights can be as effective as other physical therapies such as Kegel exercise, bladder retraining, and electrical stimulation. However, it is advisable to use vaginal weights in combination with other treatments rather than using vaginal weights alone.

Keywords---vaginal weights, vaginal cones, urinary incontinence, urge incontinence, vaginal prolapse, pelvic floor dysfunction.

Introduction

Pelvic floor dysfunction (PFD) is a broad term that encompasses a variety of clinical symptoms caused by weak and tight pelvic floor muscles, including incontinence, chronic pelvic pain, pelvic organ prolapse, constipation, low back pain, and dyspareunia. These symptoms adversely impact the quality of life (QOL) as well. The pelvic floor is composed of muscle fibers of the levatorani muscle, ligaments, and fascia. Levatoraniis formed from the pubococcygeus, puborectalis, illiococcygeus, and coccyges, situated on either side of the pelvis. It acts as a sling to support the reproductive organs, bladder, and rectum. The muscles and ligaments that connect the pubic bone in front and the tailbone in back form the bowl of the pelvis, which lies between the sitting bones (Eickmeyer, 2017). These structures can become weak or affected throughout a woman's life due to events such as pregnancy, childbirth, surgery, being overweight, or constipation. In women, the occurrence of PFD may slowly increase, as they grow older. Approximately one-fifth of all women have one or more PFD symptoms (Oblasser et al., 2015). Urinary incontinence (UI) is the most common PFD, with an estimated 15-17 percent prevalence, while faecal incontinence (FI) affects approximately 9 percent of adult women, and pelvic organ prolapse (POP) is more difficult to quantify, with estimates ranging from 3 to 8 percent among the population (Dieter et al., 2015).

Women with mild to moderate degrees of pelvic floor dysfunction symptoms were suggested for conservative treatment initially. Conservative care often consists of lifestyle modifications, behavioraltherapy (Golmakani et al., 2014), pelvic floor physiotherapy (Gameiro et al., 2010), and medication. If incontinence continues, surgical intervention such as implantation of slings without suburethral stress or colposuspension may be suggested (Jundt et al., 2015). Evidence supports that pelvic floor physical therapy aids in retraining the muscles with or without added modalities, i.e., isometric exercise or resistance exercise based on the existing pelvic floor muscle power (Wallace et al., 2019).

Vaginal cone (VC) is a form of resistance exercise and a non-invasive approach for treating PFD in women. It helps the patient to locate the pelvic floor muscle by making them physiologically aware of it. It also helps to strengthen and tone the pelvic floor muscle (Bø, 2015; Oblasser et al., 2015). Plevnik first presented the idea of using vaginal cones to strengthen pelvic floor muscles in 1985. He advised the patients to walk for 15 minutes twice a day without making any voluntary contractions, despite their fears of losing the vaginal cone. However, pelvic floor electromyography during the usage of a vaginal cone revealed that this sensation caused an involuntary contraction of the pelvic floor musculature(Madill & McLean, 2008). Various studies have assessed the effectiveness of vaginal weights in treating PFD. However, there are controversial conclusions reached when the effectiveness of vaginal weights was compared with other conservative treatments. The reviews regarding the efficacy of vaginal weights in various PFD conditions have never been done previously. Therefore, this study was aimed to determine the effectiveness of vaginal weights compared with other interventions in reducing the symptoms of PFD.

Methods

Literature search strategy and study eligibility criteria

A qualitative and quantitative systematic review using the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guideline was conducted (Page et al., 2021). Systematic searches were carried out in the following databases: PubMed, Cochrane, CINAHL, Scielo, and Google Scholar. The keywords were arranged using Boolean markers "AND", "OR" and "NOT" in various combinations to expand or narrow down search results and findings. The keywords used to search articles are: vaginal cones, vaginal weights, physiotherapy/physical therapy management, conservative management, first and second degree uterus prolapse, bladder prolapse, cystocele, pelvic organ prolapse, utero vaginal prolapse, rectocele, cystocele, sexual dysfunction in postpartum women, middle-aged women, women in reproductive age, postmenopausal women, old age women/female, urinary incontinence, stress urinary incontinence, urge incontinence, and mixed incontinence for each database. Search using MeSH terms for the search strategy was also used, which includes pelvic floor disorder, therapy, and rehabilitation. In addition, journal reference lists and journal tables of content were screened and identified.

This study includes only randomized controlled trials, published in English and also fitting the selection criteria, namely women of age group 18 years or older, who have at least one symptom of PFD such as urinary incontinence, faecal incontinence, pelvic organ prolapses, or sexual dysfunction and are diagnosed using the following standard procedures: Pad test, I- QOL, Wexner incontinence score, FIQL, POP-Q, FSFI, and perineometry appropriately. We excluded the articles with the following elements: (i) pregnant women, (ii) intervention with a combination of vaginal cones and other treatments in the management of PFD. The selected articles were distributed to the reviewers, and their eligibility was checked by screening the title, abstract, and full text. The feedback from reviewers was discussed and resolved with consensus if there were any discrepancies.

Data extraction

The citations collected after eligibility screening were processed for data extraction. The relevant data extracted from the selected articles was updated in the data extraction sheet. The following information was extracted from the selected article: author and year of publication; title; population studied, such as middle-aged, postpartum, and post-menopausal women; intervention given to the experimental and control groups; frequency and duration of treatment; and outcome – standardized mean and standard deviation for effect size calculation. The extracted information was tabulated as per the type of PFD symptoms. Disagreements were resolved after discussions among reviewers, with each reviewer's opinion being taken into consideration and later agreed upon the argued theme.

Risk of bias assessment

The included studies were assessed using the Cochrane Risk of Bias Tool, Version 2 (ROB2).Random sequence generation (selection bias), allocation concealment (selection bias), participant and personnel blinding (performance bias), outcome assessment blinding (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and other biases are among them. Reviewers thoroughly read each article, and the risk of bias results were reported. In addition, a funnel plot was used to investigate publication and other bias in metaanalysis. They are basic scatterplots of the treatment effects measured against a scale of study size (vertical axis) from individual studies (horizontal axis). The funnel plot is focused on the accuracy that improves in predicting the underlying therapy impact as the sample size of component studies grows. Therefore, the findings of small experiments would scatter uniformly at the bottom of the graph in the absence of bias, with the scatter narrowing across larger studies. Asymmetric funnel plots may be due to publication bias (the association of publication probability with the statistical significance of study results). However, it is necessary to note that publication bias is just one of a variety of potential triggers of funnel-plot asymmetry. Sedgwick & Marston (2015) suggest that funnel plots can be used as a generalized way of analysing small study effects (the tendency for the smaller studies in a meta-analysis to show larger treatment effects) rather than a method for diagnosing particular types of biases.

Data synthesis and statistical analysis

All of the data for the final included studies on a forest plot were analysed using Cochrane Revman 5.4 to present the results. To assess the efficacy of vaginal weights in PFD, the meta-regression method was used (Forero et al., 2019).

Results

Literature search results

A total of 37 duplicate articles were deleted from a total of 560 articles. After reviewing 523 titles and abstracts from primary sources, 512 were eliminated because three were published in other languages, 460 were unrelated topics, two were case studies, three were systematic reviews or meta-analyses, 32 lacked fulltext articles, and 12 did not match inclusion criteria. Then, 11 publications were evaluated for eligibility, with 5 being excluded owing to a lack of data. As a result, 6 RCTs involving women (n = 644) were included (see Figure 1).

Characteristics of included studies

The extracted reports range from 2000 to 2020. All the included studies are randomised controlled trials. The sample size included in the study ranged from 40 to 250 in number. Vaginal cones are used as an intervention for the study group in comparison with standard treatment procedures (Table 1, Table 2, Table 3 & Table 4). In the year 2019, RizaDur et al. conducted a prospective randomised controlled study to assess the effect of vaginal cone intervention in women affected by stress urinary incontinence and compare it with trans-obturator tape (TOT) surgery. This study involved forty (40) women divided into two equal groups. One group was treated with vaginal cones and the other group underwent a trans-obturator tape procedure. The participants were observed for up to six months post-treatment. The Wagner's quality of life questionnaire was used as an outcome measure for assessing the improvements (Dur et al., 2019). In the year 2014, NahidGolmakani and colleagues performed a randomised trial to assess the efficacy of vaginal cones in stress urinary incontinence in comparison with a behavioral intervention program. The study was conducted among sixty (60) women aged 26 to 65 years old. The study group was trained with pelvic floor muscle exercise using vaginal cones, whereas the control group was given behavioral intervention for 12 weeks with follow-up sessions every two weeks. The pad test was employed as an objective measure, whereas the detecting stress urinary incontinence severity questionnaire, leakage index, and three-day urinary diary were used as subjective measures (Golmakani et al., 2014). Rodrigo A Castro and colleagues in the year 2008 performed a single-blinded randomised controlled trial to assess the effect of vaginal cones in treating stress urinary incontinence. A total of 118 participants were selected and randomly assigned to different intervention groups, out of which 31 were for pelvic floor exercises, 30 for electrical stimulation, 27 for vaginal cones, and 30 as an untreated control group. The Pad test, quality of life questionnaire (I-QOL), and urodynamic stress urine incontinence as an outcome measure were used to assess pretest and posttest outcomes during the six-month research period (Castro et al., 2008).

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Figure 1. PRISMA flow diagram

Table 1 Summary description of included studies

Study characteristics	Is vaginal weight therapy effective in treating pelvic floor dysfunction?					
-	Studies (N=6)	Participants (N=650)				
Study design						
Randomized control trial	6 (100%)	650				
Observational	0	0				
Types of patient						
Stress urinary incontinence	6 (100%)	650				
Others	0	0				
Country						
Developed	3 (50%)	458				
Developing	3 (50%)	192				
Experiment arms						
2 arms	3 (50%)	211				
>2 arms	3 (50%)	439				
Comparing with other therapy						
Pelvic floor exercise	5 (83.3%)	610				
Other therapy	1 (16.7%)	40				
Assessment of efficacy						

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Quantitative	0	0
Qualitative	0	0
Combined	6 (100%)	650
Original effect size		
Cross-tabulation analysis	5 (83.3%)	419
ORs and 95% Cis	1 (16.7%)	231

Kate S. Williams and associates, in the year 2006, conducted a controlled trial to analyse the effect and cost-effectiveness of pelvic floor muscle therapies (PFMT) for urodynamic stress incontinence and mixed incontinence. It is a three-arm randomised controlled trial. Participants aged forty years and above with the given condition were involved for whom the behavioral intervention had previously failed. A total of 79 women received intensive PFMT, 80 received vaginal cone exercises, and 79 received the primary behavioral intervention for a period of three months. Williams et al. (2006) used the frequency of primary incontinence episodes, pad test, patient perception problems, pelvic floor assessment function, pad usage, and influence on quality of life as outcome measures.

Table 2
Characteristics of the included studies in the meta-analysis

No.	Author	Countr	Populatio	Type of	Parity	Age (Years)	BMI
	/ Teal	y of Study	11	ITalling			(CIII/Kg²)
1.	Seo et al. 2004	Korea	Patient with SUI	VC (n=60) ES (n=60)	2.7 ± 2.1 2.3 ± 2.0	44.5 ± 12.1 42.7 ± 11.3	59.7 ± 7.4 56.8 ± 8.7 (Body weight)
2.	Castro et al. 2008	Brazil	Women with SUI	VC (n=24) PFMT (n=26) ES (n=27) Control (n=24)	N/A N/A N/A N/A	$52.6 \pm 11.2 \\ 56.2 \pm 12.5 \\ 55.2 \pm 12.8 \\ 52.6 \pm 11.2$	$24.1 \pm 4.6 25.9 \pm 5.0 21.9 \pm 3.9 26.9 \pm 5.1$
3.	Bo et al. 1999	Norway	Women with genuine stress incontinen ce	VC (n=27) PFMT (n=25) ES (n=25) Control (n=30)	$2.6 \pm 1.0 \\ 2.3 \pm 0.8 \\ 2.4 \pm 1.0 \\ 2.4 \pm 0.9$	49.2 ± 10.6 49.6 ± 10.0 47.2 ± 10.1 51.7 ± 8.8	$25.3 \pm 4.4 25.1 \pm 2.8 24.9 \pm 3.2 25.8 \pm 3.7$
4.	Dur et al. 2019	Turkey	Women with SUI	VC (n=20) TOT (n=20)	3.1 ± N/A 3.5 ± N/A	47.2 ± 10.6 50.1 ± 5	30.3 ± 5.6 32.1 ± 4.9
5.	William s et al. 2006	UK	Women with SUI	VC (n=80) PFMT (n=79) Control (n=79)	3 ± N/A 2 ± N/A 4 ± N/A	58.2 ± 9.4 55.9 ± 8.5 56.7 ± 10.6	N/A N/A N/A
6.	Golmak	Iran	Women	VC (n=25)	3.5 ± 1.3	45.6 ± 4.5	24.8 ± 2.6

ani et	with SUI	BIP (n=26)	3.2 ± 1.2	45.5 ± 4.7	25.6 ± 2.2
al.					
2014					

Note: Data are the mean ± SD. All characteristics refer to VC: vaginal cone group; PFMT: pelvic floor muscle training group; ES: electrical stimulation group; TOT: transobturator tape group; BIP: behavioral intervention program; N/A: not appear.

In 2004, Ju Tae Seo and colleagues conducted a study comparing the effects of vaginal cones with pelvic electrical stimulation (FES) biofeedback. One twenty (120) women who required non-surgical treatment participated in the study and were divided into two groups for intervention, respectively. The study was conducted for a duration of six weeks, with two training sessions each week. Quality of life and objective symptoms are used as outcome measures (Seo et al., 2004). Kari Bo et al. (1999) conducted a single-blind randomized controlled trial by comparing the efficacy of vaginal cones with pelvic floor exercises, electrical stimulation, and an untreated control group for genuine stress incontinence. A total of 107 women with diagnosed genuine stress incontinence were involved in the study, with a mean age of 49.5 and a mean duration of symptoms of 10.8 years. Of those, 25 women were trained with pelvic floor exercise, 25 used intermittent vaginal electrical stimulation, 27 used vaginal cones, and 30 were in the untreated control group. Outcome measures included the pad test with standardised bladder volume and an individual report of severity (Bo et al., 1999).

Table 3
Characteristics of various pelvic floor training intervention of the studies included
in the meta-analysis

No.	Author/ Year	Type of Training	Frequency (week ⁻¹)	Session Length (min)	Duration (weeks)	No of Session s
1.	Seo et al.	VC (n=60)	7	5	6	42
	2004	FES (n=60)	2	20	6	12
2.	Castro et al. 2008	VC (n=24) PFMT (n=26) ES (n=27) Control (n=24)	3 3 3 -	45 45 20 -	24 24 24 -	72 72 72 -
3.	Bo et al. 1999	VC (n=27) PFMT (n=25) ES (n=25) Control (n=30)	7 1 7 -	20 45 30 -	24 24 24 -	168 24 168 -
4.	Dur et al.	VC (n=20)	14	15	21	294
	2019	TOT (n=20)	-	-	-	-
5.	Williams	VC (n=80)	14-21	10-15	12	168-
	et al. 2006	PFMT (n=79)	28	-	12	252

		Control (n=79)	-	-	-	336
						-
6.	Golmakan	BIP (n=26)	-	-	-	-
	i et al.,	VC (n=25)	14	15	12	168
	2014					

Note: Data are the exact range. All characteristics refer to VC: vaginal cone group; PFMT: pelvic floor muscle training group; ES: electrical stimulation group; TOT: transobturator tape group; BIP: behavioral intervention program; N/A: not appear.

 Table 4

 Outcome measures and test values of the studies included in meta-analysis

SI	Author / Year	Title	Sa mpl e size	Populati on	Interven tion	Compariso n	Outcom e Measur e	Pre-test values	Post-test values
1.	Dur et al. 2019	The impact of vaginal cone therapy on stress urinary incontinence compared with transobturator tape	40	Women with urodyna mic SUI	Vaginal Cone	Transobtu rator tape (TOT)	Pad test	VC – 33.41 TOT - 63	VC - 23.4 (39.5) TOT - 11.6(28.6)
2.	Golma kani et al. 2014	Behavioral Intervention Program versus Vaginal Cones on Stress Urinary Incontinence and Related Quality of Life: A Randomized Clinical Trial	51	Women with SUI	Vaginal Cone	Behavioral Interventio n	Pad test	VC -36.1 BI- 35.8	VC - 19.5 (5.2) BI - 12.8 (3.8)
3.	Castro et al. 2008	Single-blind, randomized, controlled trial of pelvic floor muscle training, electrical stimulation, vaginal cones, and no active treatment in	101 VC: 80; PF MT; 79; Con trol: 79	Women with SUI	Vaginal Cone	Pelvic floor exercises, Electrical stimulatio n, Untreated control	Pad test	VC - 36.6 PFMT - 39.7 ES - 37 Control - 37.9	VC - 8.0 (12.6) PFMT - 8.4 ES -9.1 Control - 21 (18.5)

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		the management of stress urinary incontinence							
4.	Willia ms et al. 2006	A randomized controlled trial of the effectiveness of pelvic floor therapies for urodynamic stress and mixed incontinence	231	Women with SUI	Vaginal Cone	Pelvic floor muscle training, Untreated control	1-h pad test	VC:5.0 (1.00- 18.0) PFMT:4. 2(2.0- 19.7) Control:3 .6(1.0- 15.9)	VC:2.0 (0.0-8.8) PFMT:2.0(0.3-5.0) Control- 2.0(0.0- 7.8)
5.	Seo et al. 2004	A Randomized Prospective Study Comparing New Vaginal Cone and FES- Biofeedback	120 VC: 60 Con trol: 60	Patient with SUI	Vaginal Cone	FES- Biofeedbac k (BFB)	Pad test	VC - 6.51 (2.55) FES-BFB - 5.56(6.0 5)	VC-3.72 (6.73) FES-BFB - 3.38 (5.37) 277
6.	Bo et al. 1999	Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women	107	Women with genuine stress incontin ence	Vaginal Cone	Pelvic floor exercises, Electrical stimulatio n, Untreated control	Stress pad test	VC – 48.4 (51.2) PFMT- 38.6 ES -56 Control - 51.4	VC- 33.7(20.8 - 46.6)(32.6 1) PMFT - 8.4 ES - 25.8 Control - 38.7(24.2 -49.6) (34.01)

Note: Data are the mean range. All characteristics refer to VC: vaginal cone group; PFMT: pelvic floor muscle training group; ES: electrical stimulation group; TOT: transobturator tape group; BIP: behavioral intervention program; SUI: stress urinary incontinence

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Risk of bias results

The ROB2 results are shown in Figures 1 and 2. In terms of adequate sequence generation and addressing incomplete data, all six RCTs had a low ROB, and two RCTs (Golmakani et al., 2014; Seo et al., 2004) had an unclear ROB in three dimensions. Five RCTs (Bo et al., 1999; Castro et al., 2008; Dur et al., 2019; Golmakani et al., 2014; Williams et al., 2006) had a low ROB, and one RCT (Seo et al., 2004) had an unclear ROB when it comes to allocation concealment. Three RCTs (Bo et al., 1999; Castro et al., 2008; Golmakani et al., 2014) had a low ROB, one RCT (Williams et al., 2006) had a high ROB, and two (Dur et al., 2019; Seo et al., 2004) had an unclear ROB when it comes to participant and personnel blinding. Three RCTs (Bo et al., 1999; Castro et al., 2008; Seo et al., 2004) had a low ROB, whereas three studies (Dur et al., 2019, Golmakani et al., 2014; Williams et al., 2006) had an unclear ROB. Incomplete outcome data from all six RCTs revealed low ROBs.Four RCTs had low ROB in selective outcome reporting (Bo et al., 1999; Dur et al., 2019; Seo et al., 2004; Williams et al., 2006), while two RCTs had unclear bias in other sources of bias (Golmakani et al., 2014; Seo et al., 2004).

Out of the six RCTs identified in this study, three studies were found to have patients blinded (Bo et al., 1999; Castro et al., 2008; Golmakani et al., 2014) and three studies were found to have assessors blindfolded (Bo et al., 1999; Castro et al., 2008; Golmakani et al., 2014). (Bo et al., 1999; Castro et al., 2008; Seo et al., 2004). Patients completed supplementary self-reported subjective questionnaires in four RCTs (Bo et al., 1999; Castro et al., 2008; Seo et al., 2006). In five trials, the treatment allocation was kept secret (Bo et al., 1999; Castro et al., 2006). In five trials, the treatment allocation concealment and blinding methodologies seem to be more likely to show exaggerated treatment effects and, as a result, might be less reliable (Schulz, 2001).

The effect size was plotted on the horizontal axis against the reciprocal of the standard error of the estimated effect rather than the sample size on the vertical axis for the trials identified. As Sterne (2001) reiterated, the statistical power of a trial determined by factors in addition to sample size, such as the standard deviation of responses for continuous outcomes. From the above funnel plot, there was no study found at the bottom of the plot, indicating all studies have a reasonable study size. Following the assessment of potential bias, the funnel plot for the effect size (mean difference between post- and pre-intervention urinary loss in urinary incontinence patients) of all six articles was noticeably symmetrical, indicating that there was no significant publication bias, as four studies were located inside the plot and two studies were located outside the plot but higher up in the contour-enhanced funnel (see Figure 3).



Figure 2. Risk of bias summary: review authors' judgments about each item's risk of bias for each included study

Note: +: low risk of bias; -: high risk of bias; ?: unclear.



Figure 2. Risk of bias graph: review authors' judgments about each item's risk of bias presented as percentages across all included studies



Figure 3. Funnel Plot for publication bias analysis

Note: MD: mean difference; SE: Standard error

Results of Meta-analysis

The results of the meta-analysis of included studies are represented in Figure 4. In the forest plot below, the red squares represent the weight of each study, which is the influence of the study had on the result. The bigger the square, the larger the weight. Thus, articles written by Williams et al. (2006) carried the largest weight. The horizontal line across each square is the 95% confidence interval, with the longer the line, the wider the confidence interval, the less reliable the result is. Besides, the vertical line is the line of no effect and indicates the separation between non-vaginal weight and vaginal weight. A study by Williams et al. (2006) falls into this category of no effect. However, a study by Seo et al. (2004), with the square very near to the line of no effect, seems to favour the control group.

	Exp	erimen	tal	(Control			Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI	IV, Fixed, 95% CI
Bo et al 1999	33.7	32.6	27	38.7	34	30	12.4%	-0.15 [-0.67, 0.37]	
Castro et al 2008	8	12.6	24	21	18.5	24	9.6%	-0.81 [-1.40, -0.22]	
Dur et al 2019	23.4	39.5	20	11.6	28.6	20	8.6%	0.34 [-0.29, 0.96]	
Golmakani et al 2014	19.5	5.2	25	12.8	3.8	26	8.6%	1.45 [0.83, 2.08]	
Seo et al 2004	3.72	6.73	60	3.38	5.37	60	26.1%	0.06 [-0.30, 0.41]	- - -
Williams et al 2006	2	20.08	80	2	17.69	79	34.7%	0.00 [-0.31, 0.31]	+
Total (95% CI)			236			239	100.0%	0.07 [-0.11, 0.26]	•
Heterogeneity: Chi² = 29.02, df = 5 (P < 0.0001); l² = 83%									
Test for overall effect: Z = 0.78 (P = 0.43) Fr									Favours [experimental] Favours [control]

Figure 4. Forest plot on effect size of vaginal weight on pelvic floor dysfunction

Based on the forest plot, only one study crossed the vertical line. Therefore, the article by Castro et al. (2008) supported vaginal weight as an effective treatment in reducing symptoms of PFD when compared to other treatments. Bo et al. (1999) found negative results despite crossing the vertical line more than half the time, favoring vaginal weight.Four studies showed no effects for both the interventional and control groups. Only one study (Golmakani et al., 2014) supported the use of non-vaginal weight. The remaining four articles (Bo et al., 1999; Dur et al., 2019; Seo et al., 2004; Williams et al., 2006) refuted the choice of vaginal weight treatment as an effective treatment since those studies did not cross the vertical line. The pooled effect estimates concluded as equivocal results depicted with blue diamond that there was no efficacy for both vaginal weight and non-vaginal weight treatment.

Discussion

The purpose of this meta-analysis was to analyse the randomised clinical trials that investigated the efficacy of vaginal weights in pelvic floor dysfunction when compared to various types of other interventions by using the pad test, I-QOL, FIQL, POP-Q, and FSFI as objective measurements to determine whether vaginal weights are more useful than current standard interventions. The results of the review suggested no significant difference in effectiveness between vaginal weight and non-vaginal weight treatment groups, even though there are some results that support the use of vaginal weight. Four studies preferred to use non-vaginal weight treatment since those studies did not cross the vertical line (Figure 4), even though the context of these studies did support the use of vaginal weights.

Unfortunately, no relevant studies evaluating the effectiveness of vaginal cones and weights in faecal incontinence, pelvic organ prolapse, and sexual dysfunction were found. For faecal incontinence, there were various studies that used electrical stimulation (e.g., posterior tibial nerve stimulation and sacral nerve stimulation) and biofeedback (BF) but not resistance training using weights in the treatment session. An observational study done by Kuo et al. (2015) showed that electric stimulation (ES) and biofeedback (BF) are successful in managing faecal incontinence, resulting in an increased quality of life (QoL) for low rectal cancer patients following intersphincteric resection (ISR) (Kuo et al., 2015). In cases of pelvic organ prolapse, the intervention that is most commonly used is PFMT. Both Wiegersma et al. (2014) and Stüpp et al. (2011) conducted independent randomised controlled trial (RCT) research on the efficacy of PFMT for pelvic organ prolapse therapy and reported that this contributed to significant progress. In addition, to achieve efficacy in sexual arousal, electrical stimulation, biofeedback, and pelvic floor muscle training are recommended.

Regarding the effectiveness of vaginal weights compared to other interventions in urinary incontinence, our meta-analysis showed that the results could not be generalised as there were no significant differences observed between vaginal weight treatment and other physical therapies. Some studies, for instance, the study by Seo et al. (2004), which declared that 91.6% and 88.3% of biofeedback and vaginal cone groups, respectively, reported an increase in the degree of incontinence. The results of the pad experiments of both groups in the study were greatly changed (Seo et al., 2004).

According to Castro et al. (2008), a negative pad test with a consistent bladder volume was found in 12 (46%) of the patient populations in the pelvic floor muscle training group, 13 (48%) in the electrical stimulation group, 11 (46%) in the vaginal cone group, and only 2 (8.0%) in the untreated control group. Pad weight decreased significantly in all categories, but when the researchers analysed the data by group, they discovered that patients seeking intensive therapy reported a significant decrease in pad weight compared to the control group (p = 0.003). When evaluating other outcome measures, they suggested that pelvic floor muscle training is preferable to electrical stimulation and vaginal cones in controlling real-time stress incontinence (Castro et al., 2008).

However, according to Bo et al. (1999), exercising the pelvic floor muscles is preferable than electrical stimulation and vaginal cones in the treatment of genuine stress incontinence. Pad test leakage was reduced more successfully in the pelvic floor muscle exercises group (-30,2 g; -43,3 to 16,9) than in the electrical stimulant (-7,4 g; -20,9 to 6,1) and vaginal cones (-14,7 g; -27,6 to -1,8). One person in the control group, 14 in the pelvic floor exercise group, three in the electrical stimulation group, and two in the vaginal cones group no longer had an issue after the experiment was completed (Bo et al., 1999).

A study byWilliams et al. (2006) examined the self-reported performance in three groups: pelvic floor muscle training (PFMT), vaginal cones (VC), and control groups for three months. After accounting for baseline findings, the proportion of individuals who described each symptom as light or no concern, as well as being content with current symptoms, did not differ substantially between the three groups. While there were no differences in performance between the groups at the start of the trial, they all improved over time (from baseline) (Williams et al., 2006).

Golmakani et al. (2014) conducted a study in which vaginal cones (VC) were compared to behavioral rehabilitation programmes (BRP). The participants in the study were divided into two groups: VC and BRP. In terms of the participants' outcome, stress urinary incontinence (SUI), leakage score, urine leakage in the 1hour pad examination, daytime urinary frequency, nighttime urinary frequency, and urinary incontinence showed no significant variations between the groups. However, in both groups, there was a significant (p<0.001) reduction in the incidence of leakage on pad tests after 8 and 12 weeks of intervention. In the same study the improvements in the leakage rate on the pad test were found to be larger in the vaginal cone (VC) group (p = 0.008). However, when VC was compared to surgical management, it was discovered to be less successful than the transobturator tape (TOT) surgical procedure, which has a higher success rate and lower complication rate. According to Dur et al. (2019), despite significant reductions in pad weights in both groups, the TOT group was found to be better than the VC group at both the 6th week and 6th month follow-ups. Negative stress tests were more prevalent in the TOT group than in the VC group (85% vs. 50% at 6 weeks and 75% vs. 50% at 6 months, respectively) (p<0.05). As a result, VC should not be treated as a surgical therapeutic alternative (Dur et al., 2019). Vaginal cones are generally helpful in the treatment of urine incontinence. However, there were no significant differences when compared to other treatment techniques. The advantage is that vaginal cones are simple to employ at home and help with pelvic floor muscle strengthening. Furthermore, vaginal cones may be used alternately or in conjunction with other treatments.

Strengths of the review

However, no previous meta-analyseshave been found that summarize the comparison between vaginal cones and other treatments in the management of various pelvic floor dysfunctions. In the present study the variables suspected to influence the results were narrowed down through appropriate inclusion and exclusion criteria.

Limitations

The minimal number of clinical trials included in the meta-analysis might be the primary limitation of this research. There was no article with inclusion criteria that compared the effectiveness of vaginal weights with other treatments in reducing symptoms of faecal incontinence, pelvic organ prolapse, and sexual dysfunction. Differences in population characteristics (e.g., age, BMI, parity, race, or city in which the study was conducted) and training protocols (e.g., frequency and duration between different treatments) could be affecting our results, masking the vaginal cone effect due to the large number of training-related variables involved. The heterogeneity was caused by variation in treatment in the control group, ranging from surgery, behavioral, biofeedback, and pelvic floor muscle exercise to an untreated approach.

Recommendations

As there was lack of available studies in this field, it is recommended to conduct more experimental study to assess effectiveness of vaginal cone in fecal incontinence, pelvic organ prolapse and sexual dysfunction while compared to other treatments. More relevant articles are needed for future similar study to summarize the efficacy of vaginal cone in pelvic floor dysfunction.

Conclusion

In conclusion, vaginal weights can be equally helpfulas effectively as other physical therapy interventions such as pelvic floor muscle training, behavioral therapy, and electrical stimulation. It is easier and more convenient to use compared to electrical stimulation and can aid in pelvic floor muscle training. This analysis shows there is no significant difference found between the effectiveness of vaginal weights and other treatments. Thus, the vaginal cone can be utilized as an adjunct to other pelvic floor interventions appropriately.

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