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Review Article

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Pelvic floor muscle exercises plus biofeedback versus pelvic floor muscle exercises for patients with stress urinary incontinence: A systematic review and meta-analysis of randomized controlled trials

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ABSTRACT

Background: Stress urinary incontinence (SUI) is a widespread illness that mostly affects women, particularly those who have recently given birth or gone through menopause. The purpose of this meta-analysis is to compare the effectiveness of pelvic floor muscle exercises (PFME) plus biofeedback to PFME alone in treating SUI in female patients.

Methods: We systemically searched six electronic databases (PubMed, Scopus, and Web of Science) from inception until February 7, 2022. We included randomized controlled trials (RTCs) comparing patients who had undergone PFME plus biofeedback to PFME alone. For risk of bias-2 (RoB2) assessment, we used cochrane risk of bias assessment tool. Continuous data were pooled as standardized mean difference (SMD), and dichotomous data were pooled as odds ratio with the corresponding 95% confidence intervals (CI).

Results: 15 RCTs were included, with a total of 788 patients with SUI. The overall effect estimate between PFME+BF and PFME alone groups favored the PFME+BF group in improving PFME strength (SMD=0.33, 95% CI [0.14 to 0.52], p=.0009) and did not favor either of the two groups for quality of life (SMD=-0.22, 95% CI [-0.44 to 0.00], p=0.05), leakage (SMD=-0.10, 95% CI [-0.37 to 0.17], p=0.47), pad weight test (SMD=-0.22, 95% CI [-0.44 to 0.00], p=0.05), cure rate (odd ratio [OR]=2.44, 95% CI [0.52 to 11.42, p=0.26), and social activity (SMD=0.66, 95% CI [-0.04 to 1.36], p=0.07).

Conclusion: BF addition to PRME improves cure rate and PFME strength without affecting leakage or quality of life. Healthcare providers must consider patient safety and comfort while choosing BF devices with PFME. SUI management strategies should include BF to improve results.

Keywords: effectiveness of pelvic floor muscle exercises, conservative therapy, components of urine incontinence

INTRODUCTION

Stress urinary incontinence (SUI) is a kind of urinary incontinence that happens when physical exertion or movement increases pressure on the bladder, producing urine leakage [1-3]. This may develop as a result of weak pelvic floor muscles, which support the bladder and urethra [2-5]. Coughing, sneezing, laughing, running, or hard lifting might cause urine to flow from the bladder due to the pressure involved [4-7]. SUI is a widespread illness that mostly affects women, particularly those who have recently given birth or gone through menopause [8, 9]. Obesity, nerve injury, and pelvic surgery are among the additional risk factors for SUI [8-10].

Conservative measures such as pelvic floor muscle exercises (PFME), weight loss, bladder training, biofeedback, and the use of absorbent items or devices are the first line of SUI therapy [5, 6, 11, 12]. Surgery could be required in some circumstances to maintain or restore the pelvic floor muscles [13, 14].

PFME is a frequent conservative therapy for SUI [6, 15-18]. Strengthening the pelvic floor muscles as part of this therapy aids in improving bladder control and lessening the consequences of incontinence [17]. Nevertheless, some women can struggle to complete the PFME accurately, which might result in suboptimal treatment results [19]. The use of biofeedback has been suggested as a complement to PFME for SUI or even as an alternative for PFME and other conventional therapies [20-23]. This approach makes use of tools that provide women with immediate feedback on the activity of

their pelvic floor muscles, enabling them to improve their workout methods and get better results [22].

The usefulness of PFME alone or in conjunction with biofeedback for the treatment of SUI has been examined in a number of research to date [22, 24]. The outcomes of this research, however, are often contradictory, making it challenging to choose the best strategy. To solve this problem, a meta-analysis is required, which synthesizes the findings of much research to provide a more solid and statistically significant conclusion.

The purpose of this meta-analysis is to compare the effectiveness of PFME plus biofeedback to PFME alone in treating SUI in female patients. Changes in incontinence symptoms, quality of life, and pelvic floor muscle strength are the main outcome measures of interest. The findings of this research will have significant ramifications for the treatment of this widespread and incapacitating disorder and will aid in directing clinical judgement for medical professionals and SUI patients.

METHODS

We followed the principles outlined in the PRISMA declaration while publishing this systematic review and meta-analysis [25]. Cochrane handbook of systematic reviews and meta-analyses of interventions was strictly followed throughout every step in this article [26].

Eligibility Criteria

Studies were considered for our analysis if they met the following requirements:

1. Population: Female patients with SUI.
2. Intervention: PFME plus biofeedback.
3. Comparator: PFME alone.
4. Outcome: Pelvic floor muscles strength, quality of life, leakage, pad weight test, cure rate, and social activity.
5. Study design: Human RCTs only will be included.

Studies provided as abstracts only or theses, studies for which complete full-texts were not readily accessible, research using animals or in vitro, observational studies, review articles, case reports, and case series, as well as studies not written in English were all excluded.

Information Sources and Search Strategy

Three databases (PubMed, Scopus, and Web of Science) have been searched using MeSH terms ((stress urinary incontinence) AND (biofeedback OR feedback OR myofeedback) AND (women OR female OR girl)) to identify articles for review. The search was conducted until February 7, 2022. Language, publishing time, gender, race, or country are all unrestricted. Further, the references of the included studies were manually searched for any potentially eligible studies.

Selection Process

Using Endnote (Clarivate Analytics, PA, USA), duplicates were eliminated, and the recovered references were evaluated in two stages: the first stage included screening the titles and abstracts of all identified papers independently by two authors to determine their relevancy to this meta-analysis, and the second step involved screening the full-text versions of the identified abstracts to determine final qualification to meta-analysis. Rayyan website was used for the selecting process [27].

Data Collection Process and Data Items

Data from the included records was extracted by two impartial reviewers in a preformatted Excel spreadsheet. In addition to outcome indicators, this data will include baseline characteristics of the included studies and the study population. Disagreements will be resolved by evidence-based discussions.

Assessing Risk of Bias in Individual Studies

Using the Cochrane tool for assessment of the risk of bias-2 (RoB2), two independent reviewers will assess the quality of the included studies [28]. Risk of bias assessment included the following domains: bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in the measurement of the outcome, bias in the selection of the reported result, and other biases. The authors' judgments are categorized as "low risk," "high risk," or "some concerns" of bias. Any disagreement will be resolved with debate till a consensus is reached. If authors could not agree, a senior author will be consulted.

Synthesis Methods

For categorical variables, odds ratio/risk ratio with a 95% confidence interval (CI) were calculated to estimate the effect size and compare between intervention and control groups. For continuous variables, mean difference or standardized mean difference (SMD) with 95% CI were calculated to estimate the effect size to assess the difference in outcome measures between intervention and control groups.

Choice of Meta-Analysis Model

If there is no significant heterogeneity, study-specific estimates were pooled using a fixed-effects model; otherwise, a random-effects model was used.

Assessment of Heterogeneity

Chi-square test was used to assess the statistical heterogeneity between the studies (Cochrane Q test). The I-squared was then calculated using Chi-square statistic, Cochrane Q, using the following formula:

$$I^2 = \left(\frac{Q - df}{Q}\right) \times 100\% \quad (1)$$

Significant heterogeneity was defined as a chi-square P value of <0.1. I-square values above 50% were a sign of significant heterogeneity.

Reporting Bias Assessment

We created funnel plots to show the link between effect size and standard error in order to investigate the publication bias across research. Evidence of publication bias was evaluated using two methods:

1. Begg and Mazumdar rank correlation test (Kendall's tau) [29] and
2. Egger's regression test [30].

Certainty Assessment

We performed a sensitivity analysis to conduct a certainty assessment in order to examine the validity of the evidence

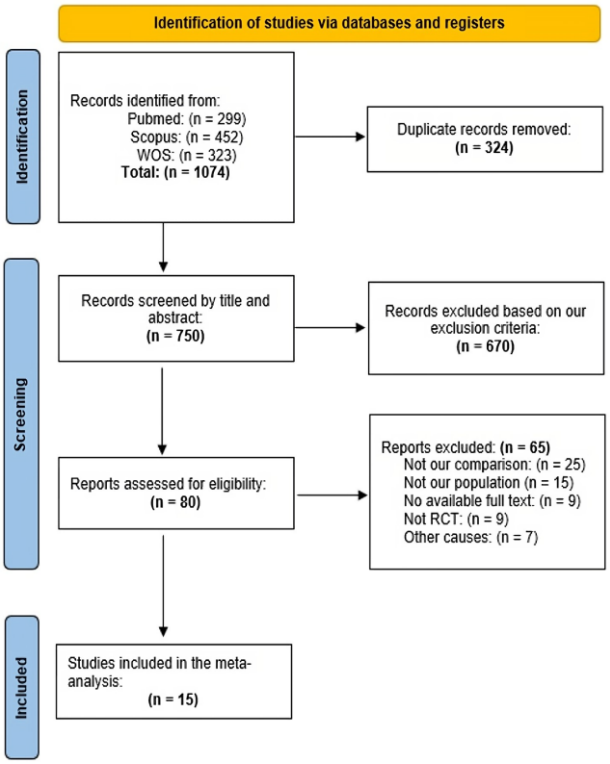

Figure 1. PRISMA flow diagram of the selection process (Source: Authors' own elaboration)

(also called a leave-one-out meta-analysis). We conducted sensitivity analyses for each outcome in the meta-analysis, eliminating one study from each scenario to ensure that the total impact size was independent of any particular research.

RESULTS

Literature Search Results

Our search for literature turned up 1,074 results. 80 articles were qualified for full-text screening after being subjected to title and abstract screening. The meta-analysis comprised 15 of these investigations. No further papers were included after manually searching the references of the listed studies.

Figure 1 depicts PRISMA flow diagram of study selection procedure.

Characteristics of Included Studies

The meta-analysis includes 15 trials with a combined total of 788 SUI patients. Patients were randomly randomized to either receive PFME plus BF or PFME alone in all trials.

Table 1 shows the summary of the studies included in this systematic review and meta-analysis.

Table 1. Summary of the studies included in this systematic review & meta-analysis

SID	Title	Design	Country	D-SUI	INT	SI	n	TD	DCI
[31]	Biofeedback and pelvic floor exercises for the rehabilitation of urinary stress incontinence	RCT	Turkey	Urodynamically	PFME	NA	20	8 weeks	Pad test results of 1 g or less were noted as cure, while a 50% or more decrease in wet weight was considered as an improvement
					PFME+BF	Myomed-932 device vaginal probe in EMG pressure mode (sensitivity 360 hPa, threshold pressure 0 hPa, sensitivity 10 ÌV, threshold 1.5 ÌV)	20		
[32]	Increase in pelvic floor muscle activity after 12 weeks' training: A randomized prospective pilot study	RCT (pilot study)	Finland	Urodynamically	PFME	NA	15	12 weeks	NR
					PFME+BF	EMG-assisted biofeedback device (FemiScan, Mega-Electronics, Kuopio, Finland)	15		
[33]	Effect of electromyographic biofeedback as an add-on to pelvic floor muscle exercises on neuromuscular outcomes and quality of life in postmenopausal women with stress urinary incontinence: A randomized controlled trial	RCT	Brazil	By international consultation on incontinence questionnaire	PFME	NA	15	4 weeks	NR
					PFME+BF	Myoelectric activation was assessed by EMGs, using a Miotool 400 system (Miotec)	16		
[34]	Treatment of stress incontinence with pelvic floor exercises and biofeedback	RCT	USA	Clinically and Urodynamically	Kegel exercise	NA	38	8 weeks	NR
					Kegel exercise+BF	Using a vaginal probe and while observing a computer screen display of their contractions.	40		
[35]	A pilot randomised controlled trial of the pelvic toner device in female stress urinary incontinence	RCT	UK	NR	PFME	NA	19	16 weeks	Subjective reports of "cure". Improvement of ICIQ-FLUTS, ICIQ-urinary incontinence short form & ICIQ-lower urinary tract symptoms quality of life questionnaires, patient satisfaction question, global perception of improvement, & estimated percent improved
					PFME+BF (pelvic toner device)	PTD (Solution Project Management, UK) with a vaginal probe	21		

Table 1 (Continued). Summary of the studies included in this systematic review & meta-analysis

SID	Title	Design	Country	D-SUI	INT	SI	n	TD	DCI
[36]	Biofeedback and physiotherapy versus physiotherapy alone in the treatment of genuine stress urinary incontinence	RCT	Denmark	Clinically & urodynamically & positive pad test	PFME	NA	15	3 months	Patient was considered cured when pad test showed a result of 0 or 1 g
					PFME+BF	Aginal surface electrode (Dantec 21L20, Skovlunde, Denmark) inserted in vagina approximately 3 cm from introitus	19		
[37]	Evaluation of the effect of pelvic floor muscle training (PFMT or Kegel exercise) and assisted pelvic floor muscle training (APFMT) by a resistance device (Kegelmaster device) on the urinary incontinence in women: A randomized trial	RCT	Iran	Urodynamic study	PFME	NA	46	3 months	Improvement considered depending on scores of IQQI, IQ, PFMS, & frequency of leakage
					APFMT	Resistence device (Kegellmaster device)	39		
[38]	Pelvic floor muscle exercise by biofeedback and electrical stimulation to reinforce the pelvic floor muscle after normal delivery	RCT	Korea	NA	PFME	NA	24	6 weeks	improvement based on IQQL score
					PFME+BF	Electrical stimulation	25		
[39]	Development of a pelvic floor muscle strength evaluation device	RCT	Thailand	International Continence Society	PFME	NA	32	16 weeks	Improving quality of life & PFM strength
					PFME+BF	Standard biofeedback machine	29		
[40]	Effect of adding biofeedback to pelvic floor muscle training to treat urodynamic stress incontinence	RCT	Norway	Pad test with standardized bladder volume	PFME	NA	34	6 months	Objective cure (2 g or less leakage on pad test) & subjective cure (incontinence no longer problematic)
					PFME+BF	Standard biofeedback machine	36		
[41]	Using the vibrance kegel device with pelvic floor muscle exercise for stress urinary incontinence: A randomized controlled pilot study	RCT (pilot study)	Malaysia	Clinical visits	PFME	NA	12	16 weeks	Subjective cure (being content after treatment)
					VKD+PFME	Vibrance kegel device	16		
[42]	Comparison of the efficacy of perineal and intravaginal biofeedback assisted pelvic floor muscle exercises in women with urodynamic stress urinary incontinence	RCT	Turkey	Urodynamic study	PFME	NA	17	8 weeks	Cure is considered with 2 g or less on a 1 hr pad test
					PFME+BF	Intravaginal P-biofeedback stimulation device or Electromyography biofeedback device	34		
[43]	Vaginal cone for postmenopausal women with stress urinary incontinence: Randomized, controlled trial	RCT	Brazil	Kings health questionnaire	PFME+VC	Vaginal cone stimulation device	15	6 weeks	NR
					PFME	NA	15		
[44]	Randomized controlled trial of pelvic floor muscle training with or without biofeedback for urinary incontinence	RCT	Japan	Urodynamic study	PFME	NA	23	12 weeks	Improvement in PFM Strength
					PFME+BF	Electromyography clinically based biofeedback	23		
[45]	A new pelvic muscle trainer for the treatment of urinary incontinence	RCT	Brazil	International Continence Society	PFME+BF	Biofeedback stimulating machine	10	12 weeks	Significant control of symptoms & improvement of quality of life
					PFME	NA	11		
[46]	Single-blind, randomized trial of pelvic floor muscle training, biofeedback-assisted pelvic floor muscle training, and electrical stimulation in the management of overactive bladder	RCT	Taiwan	International Continence Society	PFME	NA	34	12 weeks	Subjective cure is improvement of incontinence
					PFME+BF	Electromyography BAPFMT program	34		

Note. SID: Study ID; D-SUI: Diagnosis of SUI; INT: Interventions; SI: Stimulation instrument; n: Number of participants; TD: Treatment duration (follow-up period); & DCI: Definition of cure & improvement

Table 2 provide an overview of the characteristics of the included articles. In **Table 1**, we summarized the studies included in this review. Similarly, there are 17 studies in **Table 2**, where we scrutinized the included studies.

We briefly explain the baseline characteristics of the studies included in this systematic review and meta-analysis. Overall, risk of bias in the included studies varied from a high risk to a low risk according to the RoB2 checklists.

Table 2. Baseline characteristics of the studies included in this systematic review & meta-analysis

SID	INT	n	Age: M (SD)	BMI: M (SD)	P: M (SD)	DY: M (SD)	LS		PFMS		QLQ		USS	
							NQ	M (SD)	NQ	M (SD)	NQ	M (SD)	NQ	M (SD)
[31]	PFME	20	52.5 (7.9)	BW: 59.4 (6.1)	2.8 (0.5)	NR	NR	NR	Perineometry, cm H_2O	20.3 (6.2)	NR	NR	NR	NR
	PFME+BF	20	51.6 (5.8)	BW: 57.5 (5.8)	3.5 (1.1)					19.1 (4.8)				
[32]	PFME	15	50.8 (31.0-69.0)	25.8 (21.0-36.0)	3.1 (0-7)	7.3 (3.0-16.0)	Leakage index	38.5 (11.0)	Pelvic floor muscle activity (µV)	17.8 (6.8)	NR	NR	NR	NR
	PFME+BF	15	51.8 (35.0-61.0)	25.9 (21.0-36.0)	2.2 (0-5)	9.0 (1.0-30.0)		45.5 (10.1)		15.3 (4.4)				
[33]	PFME	15	59.3 (4.9)	27.7 (3.6)	2.3 (1.3)	NR	NR	NR	Maximum voluntary contraction by EMG (µv)	10.3 (2.11)	International consultation on incontinence questionnaire	11.1 (2.9)	NR	NR
	PFME+BF	16	58.4 (6.8)	27.5 (2.6)	2.6 (1)					13.8 (5.7)		12.7 (3.6)		
[34]	Kegel exercise	38	Mean: 62 y 55-60 y: 61 (45.2%) 61-70 y: 60 (44.4%) ≥71: 14 (10.4%)	NR	NR	Mean: 12.38 years	NR	NR	Pelvic floor muscle activity (µV) by EMG	2.85 (3.23)	NR	NR	NR	NR
	Kegel exercise+BF	40								3.5 (3)				
[35]	PFME	19	49.6 (36-68)	NR	Median parity of 2	5 years (6 months to 30 years)	NR	NR	NR	NR	NR	NR	ICIQ-UI short form questionnaire	6.6428 (0.98)
	PFME+BF (pelvic toner device)	21												6.765 (0.833)
[36]	PFME	15	45 (range 40-48)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	PFME+BF	19												
[37]	PFME	46	40.56 (6.18)	27.31 (2.47)	3.56 (1.95)	3.04 (3.33)	NR	NR	Percent of moderate strength	34.8%	IQQL score	53.15 (23.77)	NR	NR
	APFMT	39	39.07 (6.18)	28.74 (4.97)	3.2 (1)	3.12 (1.19)				48.7%		50.01 (10.36)		
[38]	PFME	24	30.08 (2.98)	NR	NR	NR	Frequancy of inconteince	0.04 (0.56)	Average pressure of pelvic floor muscle contraction	21.92 (14.56)	NR	NR	NR	NR
	PFME+BF	25	29.83 (2.08)					0.13 (1.01)		17.88 (10.72)				
[39]	PFME	32	48.5 (6.98)	25.74 (4.38)	1.75 (0.88)	NR	NR	NR	Vaginal squeeze pressure cm H_2O	22.48 (8.43)	IQQL score	51.08 (15.93)	NR	NR
	PFME+BF	29	46.96 (7.22)	25.87 (7.22)	1.75 (0.88)					23.16 (9.98)		53.92 (18.26)		
[40]	PFME	34	45.4 (8.1)	26.2 (4.3)	2.5 (1)	10.5 (6.6)	Leakage index	2.8 (0.5)	Pelvic floor muscle strength cmH_2O	14.4 (7.8)	NR	NR	NR	NR
	PFME+BF	36	47.8 (8.2)	25.3 (3.7)	2.3 (1)	8.8 (6.2)		2.8 (0.7)		13.6 (9.8)				
[41]	PFME	12	53.2 (14.3)	NR	2.8 (1.2)	NR	NR	NR	MOS score	2.6 (0.8)	NR	NR	SUI score	2.3 (0.9)
	VKD+PFME	16	50.7 (11)		3.2 (0.9)					2.3 (0.7)				2.6 (0.7)
[42]	PFME	17	42.82 (6.30)	29.13+/-5.16	NR	78.7 (84.79)	Pad test	11.47+/-11.57	perinometer cm H29	38.7+/-10.06	IIQ7 Score	6.70+/-4.02	NR	NR
	PFME+BF	34	42.22 (8.88)	28.8 (5.23)		75.98 (53.57)		11.02 (10.11)		35.44 (12.27)		7.67 (6.42)		
[43]	PFME+VC	15	66.33 (10.86)	27.89 (1.93)	2.4 (1.41)	41.52 (36.48)	Urinary leakage (g)	7.36 (8.76)	Pelvic floor muscle strength cmH_2O	12.6 (13.86)	KHQ-general health	35 (20.7)	NR	NR
	PFME	15	63 (10.73)	25.65 (2.79)	1.4 (1.29)	34.44 (44.28)		3.70 (4.35)		12.55 (9.2)		33.34 (18.09)		
[44]	PFME	23	58.3 (11.2)	22.5 (2.3)	2.1 (0.6)	NR	Frequency of leakage ICIQ-SF	3.4 (0.9)	Vaginal squeeze pressure cm H_2O	18.3 (9)	KHQ-general health	34.8 (24.7)	NR	NR
	PFME+BF	23	5.3 (9.8)	23.9 (4.2)	23.9 (4.2)			2.5 (1.4)		29.2 (14.3)		33.7 (24.6)		
[45]	PFME+BF	10	54.7 (6.94)	29.8 (6.36)	2.25 (0.6)	NR	NR	NR	Perinometric intensity baseline pressure cm H_2O	35.65 (10.22)	KHQ score	63.5 (16.59)	NR	NR
	PFME	11	52.09 (13.78)	30.73 (12.17)	2.25 (0.32)					39.9 (22.78)		62.4 (18.85)		

Table 2 (Continued). Baseline characteristics of the studies included in this systematic review & meta-analysis

SID	INT	n	Age: M (SD)	BMI: M (SD)	P: M (SD)	DY: M (SD)	LS		PFMS		QLQ		USS	
							NQ	M (SD)	NQ	M (SD)	NQ	M (SD)	NQ	M (SD)
[46]	PFME	34	50.09 (15.85)	22.69 (3.32)	2.47 (1.44)	NR	Frequency of leakage	0.86 (1.8)	NR	NR	NR	NR	NR	NR
	PFME+BF	34	52.32 (12.68)	23.70 (3.90)	2.91 (1.86)			0.92 (1.77)						

Note. SID: Study ID; INT: Interventions; n: Number of participants; M: Mean; SD: Standard deviation; BW: Body weight; P: Parity; DY: Duration of UI; NQ: Name of questionnaire; LS: Leakage scale; PFMS: Pelvic floor muscles strength; QLQ: Quality of questionnaire; & USS: Urinary symptoms scale

Figure 2. Risk of bias graph for each included study according to RoB2 (Source: Authors' own elaboration)

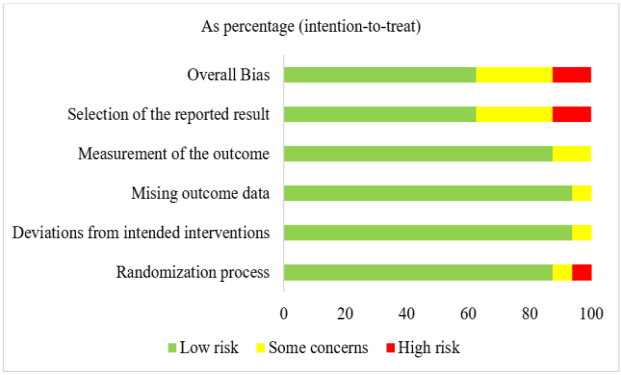

Figure 3. Summary of assessment of study quality using RoB2 (Source: Authors' own elaboration)

Figure 2 depicts risk of bias graph for each included study according to RoB2.

Figure 3 shows the summary of assessment of study quality using RoB2.

Pelvic Floor Muscles Strength

Overall effect estimate between PFME+BF and PFME alone groups in improving the pelvic floor muscle strength favors PFME+BF group (SMD=0.33, 95% CI [0.14 to 0.52], p=0.0009) (**Figure 4**). Pooled studies were homogenous (P=0.13; I^2=35%).

Quality of Life

Overall effect estimate between PFME+BF and PFME alone groups in improving the quality of life does not favor any of the two groups (SMD=-0.22, 95% CI [-0.44 to 0.00], p=0.05) (**Figure 5**). The pooled studies were homogenous (p=0.84; I^2=0%).

Leakage

The overall effect estimate between the PFME+BF and the PFME alone groups in improving the leakage does not favor any of the two (SMD=-0.10, 95% CI [-0.37 to 0.17], p=0.47) (**Figure 5**). The pooled studies were homogenous (p=0.45; I^2=0%).

Pad Weight Test

Overall effect estimate between PFME+BF and PFME alone groups in decreasing the pad weight does not favor any of the two groups (SMD=-0.22, 95% CI [-0.44 to 0.00], p=0.05) (**Figure 5**). The pooled studies were homogenous (p=0.84; I^2=0%).

Cure Rate

The pooled OR for cure rate did not favor either of the two groups: (OR=2.44, 95% CI [0.52 to 11.42, p=0.26) (**Figure 5**). The pooled studies were not homogenous (p=0.02; I^2=74%).

Social Activity

Overall effect estimate between PFME+BF and PFME alone groups in improving the social activity does not favor any of the

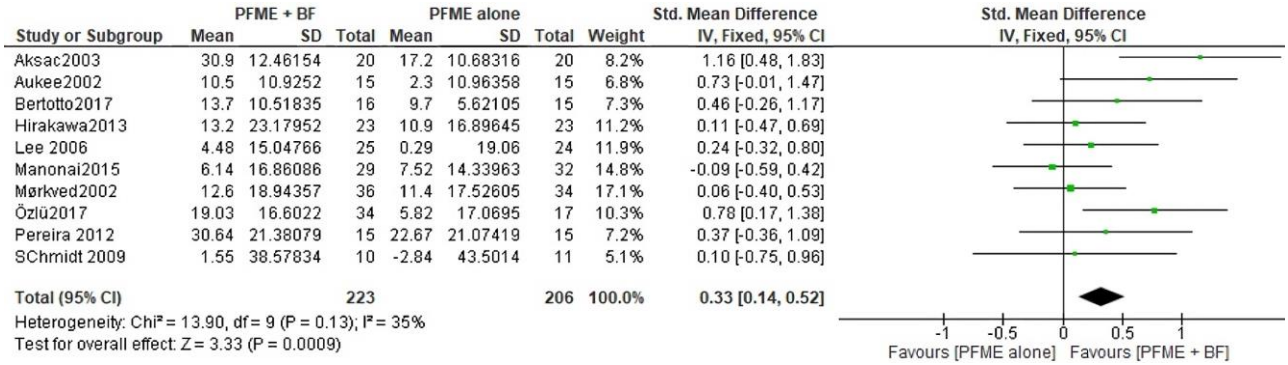

Figure 4. Forest plots comparing PFME+BF versus PFME alone in pelvic floor muscle strength (Source: Authors' own elaboration)

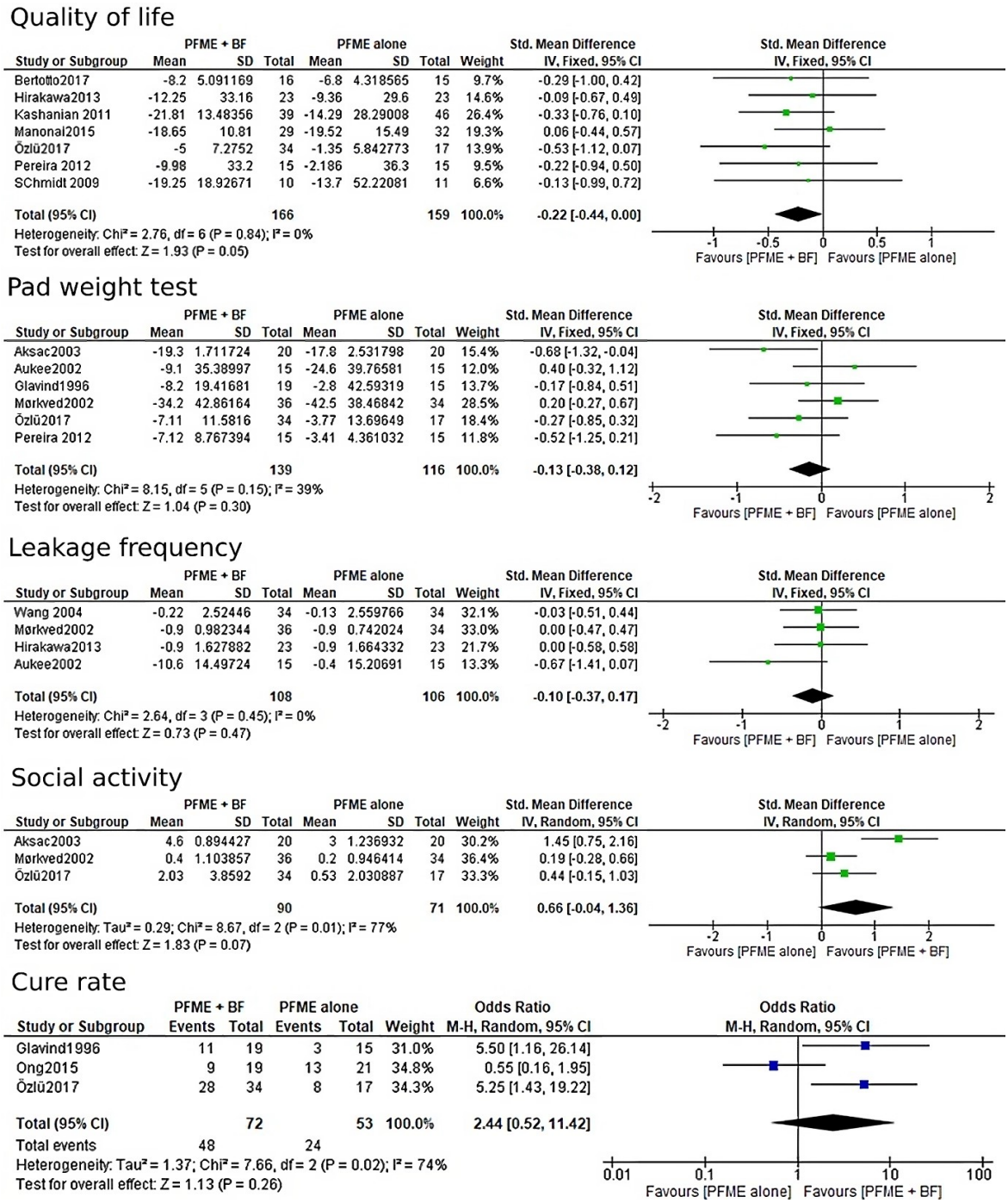

Figure 5. Forest plots comparing PFME+BF versus PFME alone in quality of life, leakage, pad weight test, cure rate, & social activity (Source: Authors' own elaboration)

two (SMD=[0.66, 95% CI [-0.04 to 1.36], p=0.07) (**Figure 5**). The pooled studies were not homogenous (p=0.01; I^2=77%).

Publication Bias Assessment

The funnel plot shows a relatively symmetrical distribution of studies on both sides of the plot, indicating a low risk of publication bias **Figure 6**. This suggests that the results of the meta-analysis are less likely to be influenced by small or unpublished studies. However, it is important to note that the precision of the effect estimates may be limited by the small sample sizes of some studies. Future research should aim to increase the sample size of studies and reduce heterogeneity to provide more precise estimates of the effect size. Egger's test slope coefficient of 1.597 suggests a positive relationship between the effect size and its precision in the meta-analysis, but the p-value of 0.110 indicates that there is no significant evidence of publication bias.

DISCUSSION

PFMT is a treatment program for urinary incontinence based on a regular contraction of the pelvic floor muscles in a fashion taught by a healthcare professional. PFMT is often the first choice of treatment for patients with SUI who are seeking conservative management options [6, 46, 48]. Biofeedback is a technique used in conjunction with pelvic floor muscle training PFMT to enhance the effectiveness of the treatment for SUI [47,

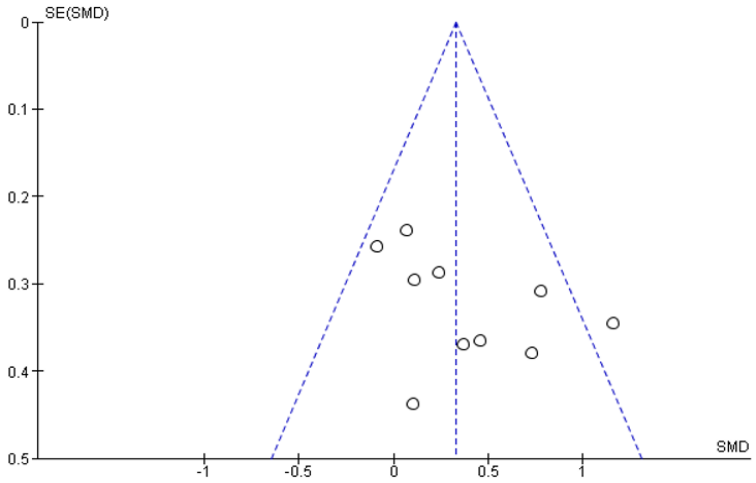

Figure 6. Funnel plot of standard error of publication bias estimation for outcome of pelvic floor muscle strength (Source: Authors' own elaboration)

49]. The combination of biofeedback mechanisms with PFMT increases its efficacy, providing patients with better control over their muscles and improving the effectiveness of their PFMT [34, 50]. The evidence of the superiority of the effect of combination therapy over PFMT alone is still unclear [48].

This study showed that the addition of biofeedback to PFMT is associated with a statistically significant improvement in several outcomes related to the management of SUI. The results showed that PFMT with biofeedback was more effective than PFMT alone in increasing the strength of the pelvic floor muscles ($p<0.0009$). However, these promising results regarding the PFM strength and cure rate, both the effect on improving quality of life, promoting social activities, and decreasing frequency and amount of leakage, showed a non-statistically significant difference between the two arms of the analysis. Taking together the add-on effect of BF to the BFMT plays a great role in the most important outcome of management of SUI despite its effect on other outcomes, but it could be explained by the subsequent causes.

Biofeedback may improve the cure rate and strength of PFME but not affect the frequency and amount of leakage or quality of life because improvement in the strength of PFME strength does not mean by default improvement of the other outcomes because it is expected to still experience leakage with a considerable amount and frequency as leakage does not directly relate to the power of PFME but also other factors as bladder capacity, individual habits and smooth muscle tone, which not related to biofeedback mechanism [48, 51, 52]. Also, it is expected that the benefits of biofeedback on these outcomes to take a longer time to be effective [53-55]. Also, the non-significant superiority of the effect of adding BF to PFME over PFME alone regarding the amount of leakage rate could be attributed to the evaluation tool. Most of the included studies depended on pad tests to reflect the amount and frequency of leakage, but this may cause some limitations on the significance of the superiority of PFME with BF over PFME alone as it is a subjective assessment, which depends on individual reporting, which is variable across individuals and across all included study participants therefore, pad test may not reflect the actual improvement of leakage improvement [56-58]. The non-significant results regarding the cure rate are attributed to the very small number of studies assessing this outcome (only three) and the difference between the studies in the definition of the cure. Moreover, when removing ong2015 [41] study to resolve the heterogeneity, the results become significant, favoring the PFME+BF group.

Non-significant superiority of BF and PFME over the PFME group alone on the quality of life of SUI patients could be explained by the concept of quality of life itself, which is variable and depends on multiple variables ranging from physical, psychological and even social domains, which are multifactorial and not relay of PFM strength, which is the primary outcome from adding BF to PFME, which is not necessary to extend its effect to other aspects of life as patient satisfaction, social interaction and quality of life improvement [59-61]. Also, the effect of SUI on the patient's quality of life is variable across patients depending on the severity of the disease, other associated diseases and even other personal expectations from treatment [62-66]. Some patients consider the reduction of the frequency and amount of leakage as a primary goal for a better quality of life, while others need additive assistance to enhance their quality of life. Finally, it is important to mention that included studies are variable in the quality-of-life assessment scale, and even the results of the effect of included studies on the quality of life are variable. This may maybe be explained by different designs of measuring this outcome according to the variable population, which also reflex the difficulty of assessing the quality of life with a standardized assessment tool. All these points may explain the non-significance difference between our two arms.

Improving PFM strength helps patients to control incontinence over time, which can increase the cure rate and improvement of SUI symptoms BF and PFME compared to the PFME group alone. It is also expected that increasing the PFM strength over time decreases the frequency of leakage, depending on the role of BF to motivate the patients to adhere to the PFME via visual and auditory information [50, 67]. Also, biofeedback could help patients in a way that is appropriate for each of them by learning how to contract the muscle in a manner suitable for each case. But we must take into consideration the type of biofeedback device, which could affect the adherence of individuals [68]. Many women do not favor the vaginal probe defendant devices due to uncomfortable maneuvers for application, which may affect adherence to exercise and also affect the outcomes of improvement. Therefore, we enhance health care providers to choose the best maneuver for each group of patients to increase the adherence rate.

Our meta-analysis included a total of 15 randomized controlled trials with a total of 788 participants, comparing PFME alone to PFME with the addition of biofeedback. The evidence from this study strongly supports the additive effect of BF to PFME on the improvement of PFME strength in the management of SUI in women. The inclusion of a large number of clinical trials adds a bigger statistical power, which has a favorable effect on the generalizability of results. Also, still, the sample size of participants needed to increase in future studies to avoid sample size limitation points. We recommend future researchers study the effect of using different biofeedback devices on the cure rate, PFME strength, adherence, and patient satisfaction to find and highlight the most accepted form to conduct the biofeedback. Further research is important to study most effective treatment protocols for SUI patients.

CONCLUSIONS

Drawing upon our discussion, we will be able to conclude that BF addition to PRME is able to improve the cure rate and the strength of PFME without a significant impact on the amount and frequency of leakage, and quality of life. The healthcare provider must consider patients' safety and comfortability while selecting the used BF device with PFME. BF is a valuable tool in improving the outcomes of controlling SUI and is recommended for its management plans. Future research should investigate the use of different leakage measurement techniques and concentrate on creating complete therapies that address both the physical and psychological components of urine incontinence. Also, when offering urinary incontinence treatment choices to patients, healthcare professionals should consider their specific requirements and preferences.

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