REVIEW

The Effect of Preoperative Pelvic Floor Muscle Training on Incontinence Problems after Radical Prostatectomy: A Meta-Analysis

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Purpose: To evaluate whether additional pelvic floow muscle training (PFMT), which began before radical prostatectomy and resumes immediately after catheter removal, will significantly improve urinary incontinence after RP.

Materials and Methods: We reviewed articles obtained from MEDLINE, CENTRAL, EBSCOHost, CINAHL, and Elsevier from July – August 2020, which compared preoperative PFMT with postoperative PMFT or non-PFMT, with continence incidence parameters. There were no restrictions on the definition of incontinence, treatment regimens, and radical prostatectomy surgical approach. The risk of bias was assessed using the Cochrane Risk of Bias Assessment Tool. A meta-analysis was also carried out to pool the effect estimates.

Results: We included 12 eligible studies in this review, 11 of which we included in the meta-analysis. The PFMT initiated preoperatively significantly reduced the incidence of persistent urinary incontinence at 1, 3, and 6 months postoperatively with an OR of 0.58 (95% CI, 0.41–0.81), 0.57 (95% CI, 0.43–0.74), and 0.38 (95% CI, 0.17-0.83). There was no difference in improvement in patients' incontinence at 12 months postoperatively [OR = 1.31 (95% CI, 0.65-2.63)].

Conclusion: PFMT initiated before radical prostatectomy significantly reduced the incidence of urinary incontinence in the first, third, and sixth months postoperatively. At 12 months postoperatively, additional preoperative PFMT did not cause a significant difference in urinary incontinence incidence.

Keywords: pelvic floor muscle training; urinary incontinence; radical prostatectomy

INTRODUCTION

Prostate cancer is the second most reported malignancy (after lung cancer) in men worldwide, with 1,276,106 new cases in 2018. Prostate cancer is responsible for 3.8% of all cancer deaths in men in men. 2018.[(1)] New cases of prostate cancer are estimated to emerge 2,293,818 cases by 2040, with projections of small variations in mortality in the form of a 1.05% increase.[(2)] About 40% of local prostate cancer patients decided to undergo radical prostatectomy.[(3)]

Urinary incontinence is a typical and predictable post-radical prostatectomy episode and is triggered by activities such as sneezing, coughing, lifting, changing positions, and exercising. After prostatectomy, persistent and disturbing urinary incontinence is a commonly reported side effect, with an incidence rate of 1% to 40% postoperatively.[(4–6)] However, this number might be much higher, depending on the definition used and the validity of the incontinence questionnaire used. Post-radical prostatectomy urinary incontinence significantly affects most men's quality of life undergoing surgical management of prostate cancer.[(7)] In assessing the quality of life of patients undergoing radical prostatectomy, incontinence was significantly associated with increased confusion, depression, and anger, and inversely related to physical and psychological healthiness.[(8)] As many as 28 and 18% of patients in the surgical group from the SPCG-4 study experienced moderate to severe discomfort due to urinary incontinence during the day or night.[(9)] Although improvements in surgical techniques have helped reduce the incidence of post-prostatectomy incontinence,[(10)] the overall rate continues to increase due to an increase in the total number of prostatectomies performed throughout the world.

Several studies recommend delaying invasive urinary incontinence therapy at least one year postoperatively.[(11,12)] Therefore, behavioral therapy was chosen in several cases as an alternative.[(13)] This noninvasive behavioral therapy consists of diet modification, bladder training, pelvic floor muscle training (PFMT), biofeedback, and functional electrical stimulation. In addition to being inexpensive and practical, they do not involve side effects.[(14)] However, some randomized controlled trials have investigated pelvic floor muscle training (PFMT) on postoperative urinary incontinence, providing conflicting evidence. While some support PFMT exercise benefits,[(15,16)] a Cochrane review in 2015 does not recommend PFM training as a first-line rehabilitation performed post-prostatectomy because there are no significant improvements in UI symptoms over time.[(17)] The protocol related to PFM training initiated preoperatively and continues postoperatively has not been established yet. The low level of evidence and the lack of systematic reviews that comprehensively review this technique's efficacy might be the contributing factor. On

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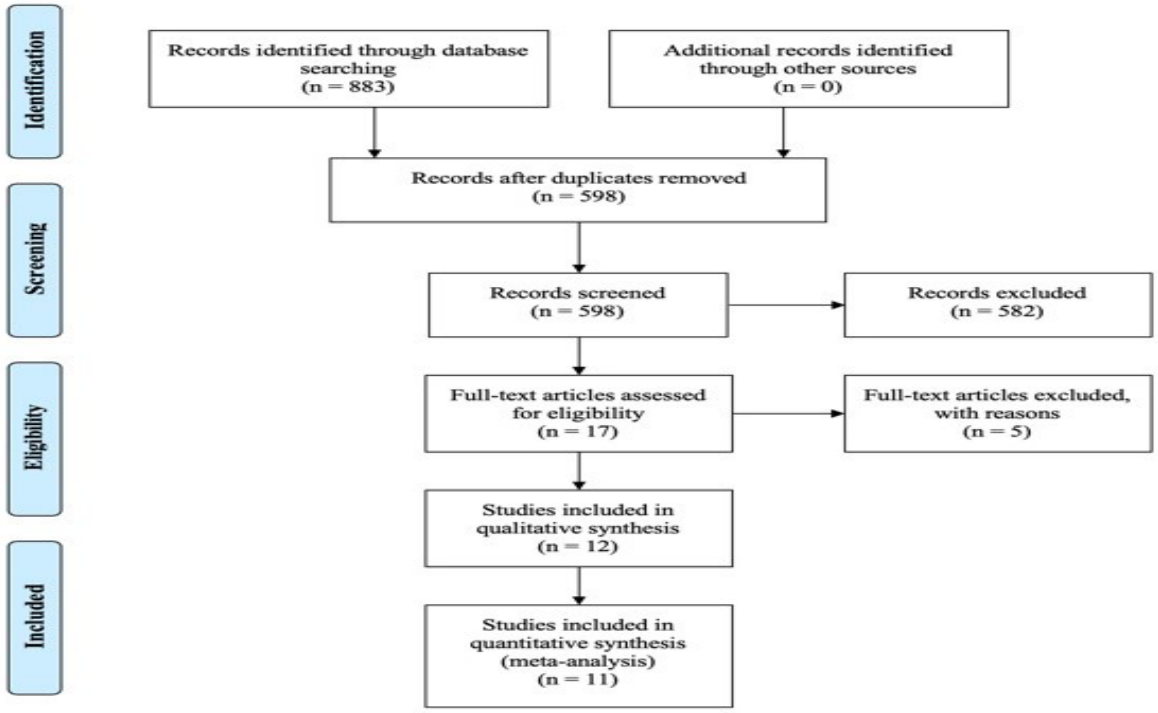

Figure 1. PRISMA flow chart describes the identification process of included articles.

the other hand, several studies had shown a significant role for PFMT when it is initiated before surgery and/or early postoperatively (< 6 weeks postoperatively).[18,19] However, some studies also report controversial results. Therefore, the authors would like to evaluate whether a PFMT which begins before radical prostatectomy and resumes immediately after catheter removal, will significantly improve urinary incontinence.

PATIENTS AND METHODS

Description of condition and intervention

This study was compiled based on the preferred reporting items protocol for systematic reviews and meta-analysis (PRISMA) statements. This study attempted to explore the effectivity of PMFT initiated preoperatively in improving urinary incontinence that occurs in patients after radical prostatectomy. Radical prostatectomy techniques were not limited to one particular approach. The use of laparoscopic and robot-assisted technology was also not a criterion for exclusion, as several studies have found there was no significant difference between the type of prostatectomy technique to urinary incontinence.20,21 Improvement of urinary incontinence was not restricted to one definition or parameter. Besides, we also did not limit the types of interventions (PMFT) given to patients, other than the timeline of intervention that must be initiated before radical prostatectomy. A follow-up duration of at least three months was a requirement that must be fulfilled by each study.

Database searching and literature screening

We conducted literature searches using five search engines (Pubmed, Cochrane, EBSCOHost, ProQuest, and Scopus) based on four electronic databases (MEDLINE, CENTRAL, CINAHL, and EMBASE). The search was conducted from July 14 to August 1, 2020. We used PICOS in the literature screening process to assess the suitability of each study for this meta-analysis, as described on supp.Table 1. We used specific keywords, which were tailored to each search engine specification. We also looked at a reference list of several reviews to broaden the scope of study searches.

Study selection

Each author selected the study independently according to inclusion and exclusion criteria. Inclusion criteria in this study included:

1. RCT or quasi-RCT studies comparing PFMT (with or without biofeedback) before and after surgery with PMFT only after radical prostatectomy;
2. English/Indonesian written articles;
3. Full-text articles available;
4. Outcomes are the percentage of patients recovering from incontinence; and
5. Were published in the last 20 years.

We included all types of surgical techniques (open radical prostatectomy, robot-assisted radical prostatectomy, and laparoscopic radical prostatectomy). The definition of incontinence of each study was also not a criterion for study selection. Exclusion criteria of this study included review articles, case reports, case series, editorial letters, studies on animals, and/or studies in the process of peer review (has not been published yet). The determination of study eligibility was determined by each author independently. After that, a full-text analysis was performed on the remaining article. Any disagreement was resolved by discussion.

Data extraction and outcome of interest

Each author conducted data extraction. We extracted the study's primary characteristics, including the first author, location, sample size, year of publication, and

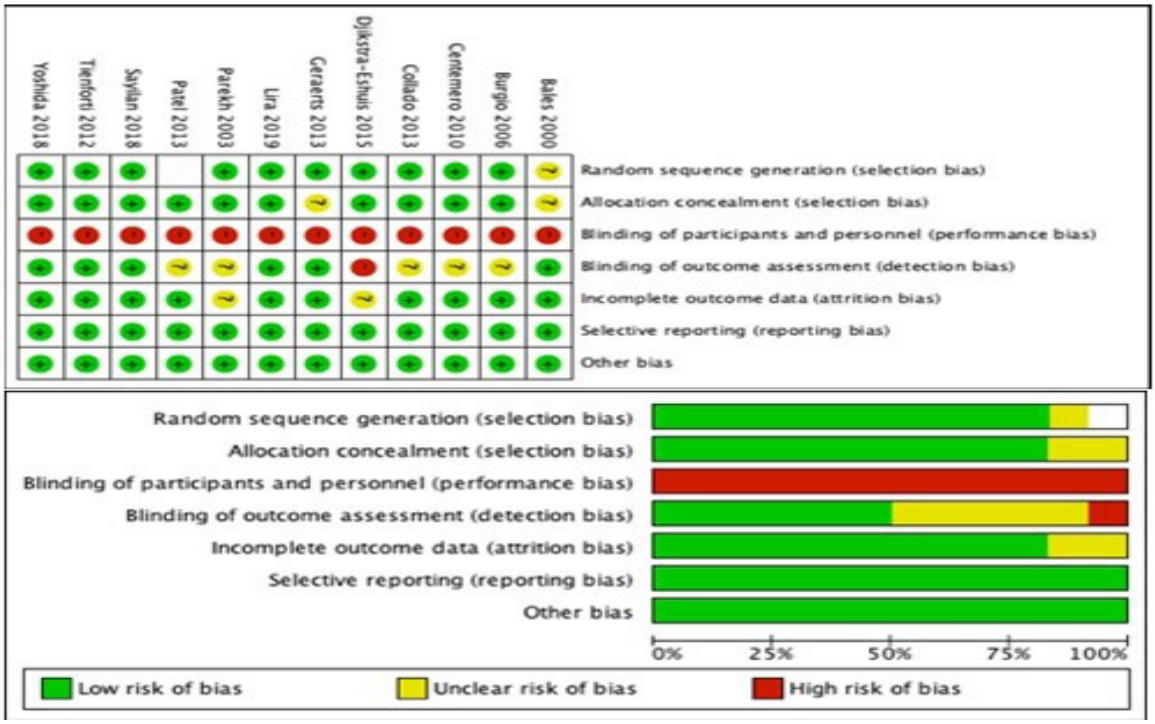

Figure 2. Risk of bias assessment of RCTs using Cochrane Risk of Bias Assessment

patient's demography. We also extracted patient baseline data, including the degree of prostate malignancy and incontinence scores before the intervention (if available). We also extracted patterns or regimens of intervention (PMFT), but there were no restrictions on the pattern of PMFT. Any discrepancies have been resolved by discussion.

This meta-analysis explored the effectiveness of PMFT initiated before radical prostatectomy compared to PFMT initiated following radical prostatectomy or no PFMT at all, in improving the recovery rate of incontinence. The output of this study was the continence rate for each independent variable. We used 2x2 contingency tabs to obtain the ORs for each study and pooled the overall OR using the Review Manager 5 application. Heterogeneity was measured by looking at the I^2 value. The I2 value greater than 50% indicated a moderate to high heterogeneity. When the high heterogeneity was found between studies, an effect estimate analysis was performed with the DerSimonian and Laird random-effects model. If heterogeneity between studies was low, fixed effect model analysis was performed using the Mantel-Haenszel methods.

Assessment of methodologic quality

This meta-analysis included only RCTs and quasi-RCTs. RCT studies' quality assessment was carried out using the Cochrane risk-of-bias tool for randomized trials (RoB 2). Studies with, at least, moderate quality were included in the overall effect estimate calculation (meta-analysis). Red dot indicated a high risk of bias of each bias criterion, while yellow meant moderate and green meant low risk of bias. Selection bias criterion was not applicable for quasi-RCT study as no random sequence was generated in patient selection. Blinding of participant was also impossible in these settings.

RESULTS

Literature search

A literature search on five electronic databases found 883 articles (first hit), and we found 285 similar articles. For 598 remaining articles, we screened and found that only 17 articles were eligible. We independently conducted a full-text analysis of the remaining 17 articles and found five articles that did not fit the PICOS that we specified in this meta-analysis. We included 12 articles in this review and 11 articles in quantitative synthesis (meta-analysis)—flowchart of this literature search described in **Figure 1**.

Study characteristics

We found 12 eligible studies based on the suitability of patient characteristics, types of interventions in the experimental and control groups, and outcomes measured in each study (**Table 1**). Eleven studies were randomized controlled trials and only 1 study with a quasi-RCT design, which did not implement randomization and patient's data was fully based on the patient's medical record. Five studies lasted for six months, four studies lasted for 12 months, and only three studies lasted for three months. Overall, the total number of patients involved in this study was 1348 patients. 3 of the 12 studies applied the same treatment regimen between the control and experimental groups,[22–24] two studies did not apply any treatment to the control group,[25,26] and the rest applied different treatment regimens. [18,19,27–31]

Risk of bias of included studies

Each author assessed each study's quality using the Cochrane Risk of Bias Assessment (RoB) tool for RCT independently. Overall, studies had a high risk of performance bias caused by the impossibility of participants and personnel blinding (**Figure 2**). Therefore, we did not exclude studies just because of the high risk of

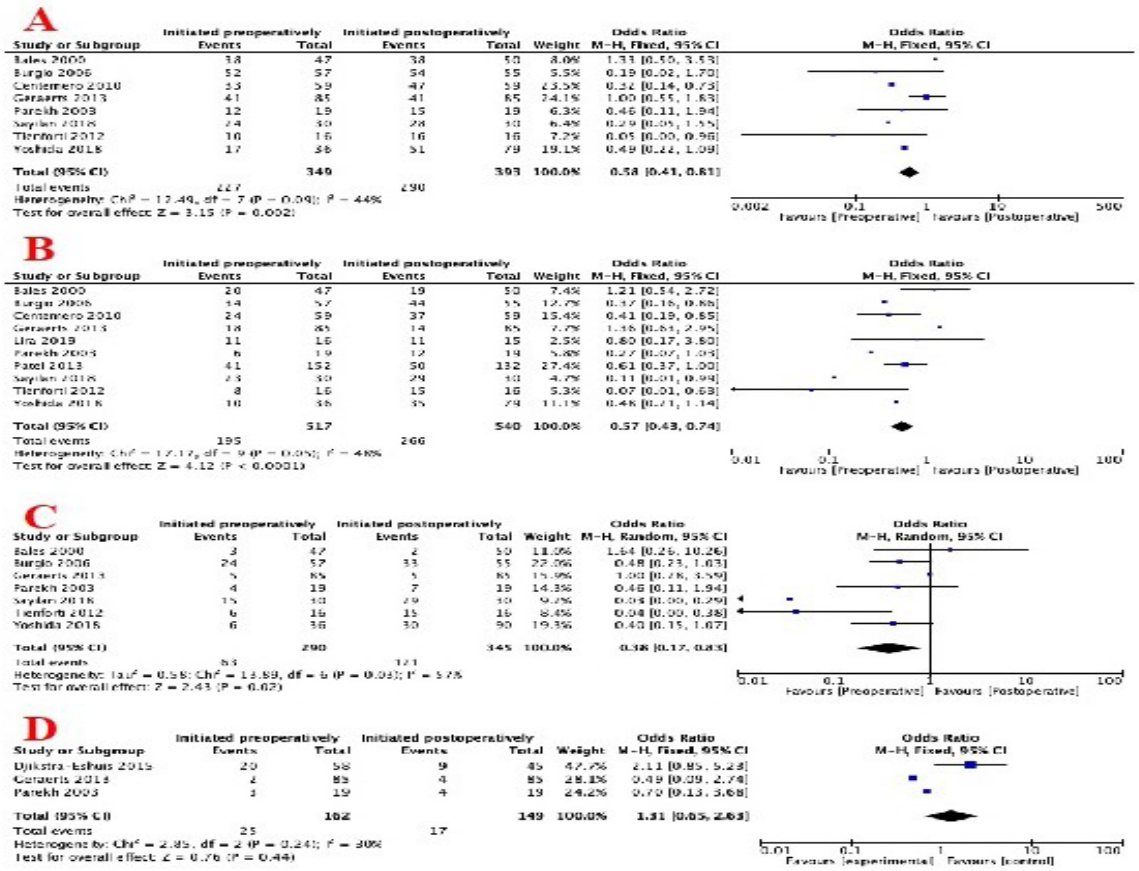

Figure 3. Forest plot shows odds ratio of getting incontinence after radical prostatectomy at several time points: **(A)** 1 month; **(B)** 3 months; **(C)** 6 months; and **(D)** 12 months.

performance bias. In general, the studies included in this meta-analysis were of good quality. The selection bias from the study of Patel et al. 2013 could not be assessed because this study was a quasi-RCT study.

Intervention regimen

We found a large variety of interventions given to patients in each study, which was generally based on each health center's protocol, where the study was conducted. PFMT accompanied and guided by a physiotherapist, followed by a biofeedback session, was the most widely

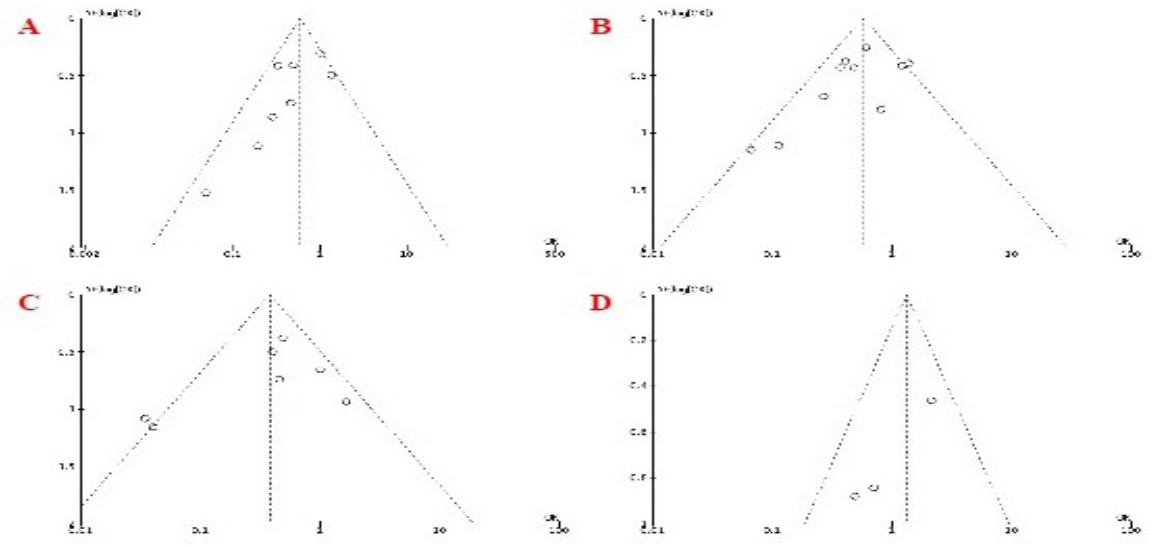

Figure 4. Funnel plot shows the distribution of studies based on the effect estimate and standard error: **(A)** 1 month; **(B)** 3 months; **(C)** 6 months; and **(D)** 12 months.

Table 1. Characteristic of the study included in this systematic review.

Author	Intervention*	Timing	Control†	N	Age (yr)	Duration
Bales et al. 2000.27	Nurse guided graded PFMT with biofeedback	4 times/day 2–4 weeks to surgery	Oral and verbal advice to perform PFMT without biofeedback	47/50	59.3/60.9	6 months
Burgio et al. 2006.19	Instruction of PFMT with single session of biofeedback	NR	Verbal advice to perform PFMT	57/55	60.7 ± 6.6/ 60.7 ± 6.6	6 months
Centemero et al. 2010.18	Physiotherapist guided PFMT with visual feedback /	Twice per week (30 minutes), 2–4 weeks preoperatively	Verbal instruction of PFMT with visual feedback	59/59	60.5 (48–68) 57.5 (46–67)	3 months
Collado et al. 2013.28	Written instruction of PFMT with weekly assisted-biofeedback session and TVA	3 weeks preoperatively	Verbal instruction of Kegel exercise	87/92	NR	12 months
Dijkstra-Eshuis et al. 2015.22	Physiotherapist guided PFMT with biofeedback and ES	30 minutes weekly, 4 weeks preoperatively	Physiotherapist guided PFMT with biofeedback and ES	65/56	63.7 ± 5.3	12 months
Geraerts et al. 2013.23	Guided PFMT with digital/EMG biofeedback	30 minutes weekly, 3 weeks preoperatively	Guided PFMT with digital/EMG biofeedback	85/85	61.88 (44–73)/ 62.04 (41–76)	12 months
Lira et al. 2019.25	Physiotherapist guided PFMT with EMG biofeedback	3 times/day 3 weeks preoperatively	Postoperative care without PFMT	16/15	63.53 ± 7.62/ 67.3 ± 5.63	3 months
Parekh et al. 2003.29	Formal instruction with 2 sessions of guided PFMT	2 sessions preoperatively	Non-formal PFMT instruction	19/19	55.5/61.6	12 months
Patel et al. 2013.24	Physiotherapist guided PFMT with visual feedback	1–4 sessions (1 hour), 4 weeks preoperatively	Physiotherapist guided PFMT with visual feedback	152/132	60 (41–76)/ 62 (44–76)	3 months
Sayilan et al. 2018.26	Guided PFMT with visual feedback	1–4 sessions (1 hour), 1 week preoperatively	No exercise instruction	30/30	63.00 ± 8.61/ 59.93 ± 6.98	6 months
Tienforti et al. 2012.30	Supervised PFMT with biofeedback	1 day preoperatively	Oral and written instructions of PFMT	16/16	67 (60–74)/ 64 (52–74)	6 months
Yoshida et al. 2018.31	Physician guided PMFT with single session US-biofeedback	1 month preoperatively	Verbal instruction of PFMT	36/80	66.5 ± 6.2/ 66.5 ± 5.8	6 months

* Interventions were given both before and after surgery; † Interventions were given postoperatively only; NR: not reported; TVA: transversus abdominis activation; ES: electrical stimulation; PFMT: pelvic floor muscle training; EMG: electromyographic; US: ultrasound

used treatment regimen.[18,22,24,25] Only the Parekh et al. (2003) study did not include biofeedback in the treatment regimen.[29] Most studies conducted training and biofeedback sessions at least once a week for 30–60 minutes per session, four weeks before radical prostatectomy. Only the Tienforti et al.[30] and Sayilan et al.[26] studies conducted therapy less than two weeks before radical prostatectomy, and two studies did not report the specific time of the PFMT therapy initiation.[19,29]

Incontinence rate at several time points

We compiled incontinence rates between studies in the form of OR patients experience post-radical prostatectomy incontinence at several time points (**Table 2 and Figure 3**). In the first 1-month after radical prostatectomy, we found that the experimental group had a significantly lower risk for incontinence after radical prostatectomy. The significance of this risk difference is was marked by the low OR and the width of the confidence interval that does did not exceed one unit [OR = 0.58 (95% CI, 0.41–0.81)]. The heterogeneity between studies was also not significant (I^2 = 44%, p = 0.09), so we performed calculations using the Mantel-Haenszel fixed-effect model.

At three months postoperatively, the incontinence rate's difference between the experimental and control groups also remained significant. The experimental group's odds ratio for incontinence compared to the control group at three months postoperatively was 0.57 (95% CI, 0.43–0.74), with no significant heterogeneity between studies (I^2 = 48%, p = 0.05). Only two studies reported that the control group reported a lower risk of persistent incontinence than the experimental group.[23,27]

Six months postoperatively, the incidence of urinary incontinence was still significantly lower in the experimental group. At this time point, the experimental group's odds ratio to the control group was 0.38 (95% CI, 0.17–0.83), with significant heterogeneity between studies (I^2 = 57%, p = 0.03). Only seven studies compared incontinence in the experimental and control groups in the 6th-month post radical prostatectomy, and only two studies reported a significantly higher incidence of persistent urinary incontinence six months postoperatively in the control group. The minimum number of studies involved in the meta-analysis for this six-month time point and the considerable variation in odds ratios between studies might become the cause of high heterogeneity between studies.

There were only three studies comparing incontinence

Table 2. Systematic review table of the experiment's outcomes.

Author	n	Continence definition	Types of prostatectomy	Incontinence (OR)				Quality
				1 mo	3 mo	6 mo	12 mo	
Bales et al. 2000	47/50	The use of ≤ 1 pad per day	NR	1.33	1.21	1.64	NR	Fair
Burgio et al. 2006	57/55	No leakage (3 consecutive weekly 1-day diaries/7-day diary)	NR	0.19	0,37	0.48	NR	Fair
Centemero et al. 2010	59/59	No urinary leakage in bladder diary and a negative stress test	ORP	0.32	0.41	NR	NR	Fair
Collado et al. 2013	87/92	Not reported	NR	NR	NR	NR	NR	Fair
Dijkstra-Eshuis et al. 2015	65/56	No leakage at all on a 24-hr pad test, PeLFIs, and KHQ	LARP	NR	NR	NR	2.11	Fair
Geraerts et al. 2013	85/85	3 days of 0 g of urine loss on the 24-h pad test	RARP and ORP	1.00	1.36	1.00	0.49	Fair
Lira et al. 2019	16/15	Patient's perception of loss of at least a few drops of urine	ORP	NR	0.80	NR	NR	Good
Parekh et al. 2003	19/19	The use of ≤ 1 pad per day	NR	0.46	0.27	NR	0.79	Fair
Patel et al. 2013	152/132	Patient-reported one pad usage/day	ORP	NR	0.61	NR	NR	Poor
Sayilan et al. 2018	30/30	ICIQ-UI score of zero	NR	0.29	0.11	0.03	NR	Good
Tienforti et al. 2012	16/16	ICIQ-UI score of zero	ORP	0.05	0.07	0.04	NR	Good
Yoshida et al. 2018	36/80	The number of days requiring a small pad (20 g)/day	NR	0.49	0.48	0.40	NR	Good

NR: not reported, ORP: open radical prostatectomy, RARP: robot-assisted laparoscopic radical prostatectomy, LARP: laparoscopic radical prostatectomy

events at 12 months post radical prostatectomy.[22,23,29] None of these studies reported significant differences between incontinence events in the experimental and control groups. Therefore, we also found something similar in the meta-analysis at that time point. We found no significant difference between the control and experimental groups on experiencing incontinence 12-month after radical prostatectomy, with the experimental group's tendency to be more susceptible [OR = 1.31 (95% CI, 0.65-2.63), $I^2 = 30\%$, $p = 0.44$].

We used a funnel plot to predict the probability of publication bias in this meta-analysis (**Figure 4**). The risk of publication bias was relatively high in several outcomes: six months and 12 months after surgery. The low number of studies assessing these outcomes, especially 12 months postoperatively, variations in patient characteristics and outcome measurement, and the inclusion of studies with low quality were thought to cause the high risk of publication bias.

Subgroup analysis was not carried out as we did not find any relevant characteristic that might influence the outcome. The types of prostatectomy (ORP, LARP, RARP) did not significantly affect the incontinence rate after prostatectomy.[20,21]

DISCUSSION

Persistent and disturbing urinary incontinence after prostatectomy is a commonly reported side effect postoperatively, with an incidence rate of 1% to 40%.[4–6] Several studies recommend delaying invasive urinary incontinence therapy at least one year postoperatively.[11,12] Therefore, behavioral therapy was chosen in some cases as an alternative.[13] This noninvasive behavioral therapy consists of diet modification, bladder training, pelvic floor muscle training (PFMT), biofeedback, and functional electrical stimulation. Apart from being cheap and practical, these therapies have never been reported to cause any side effects.[14]

Urinary continence depends on the smooth and striated muscle fibers' complex interactions that work sinergically to form a continuity mechanism. Some authors are still debating about whether incontinence after prostatectomy is due to effects on the detrusor muscle (bladder) or the sphincter. Detrusor overactivity and intrinsic sphincter insufficiency due to sphincteric injury are the most important causes of persistent incontinence after radical prostatectomy. Some reports mention that detrusor overactivity is a significant cause of postprostatectomy incontinence,[32,33] others strongly argue that even if other factors play a role, intrinsic sphincter deficiency is the main cause of UI after radical prostatectomy.[34–36] Detrusor overactivity is an incontinence pathophysiology that is corrected by PFMT. This method includes exercising specific pelvic floor voluntary muscle contractions using biofeedback, as well as coordinating and determining the time of contraction for increased intraabdominal pressure. Specific and repetitive contractions of the pelvic floor muscles can increase strength and efficiency when there is an increase in intraabdominal pressure; thus, this would suppress detrusor overactivity. Berghmans and colleagues reported that pelvic floor muscle contractions effectively held the urethra by

providing structural support to the pelvic organs; and PFMT triggers hypertrophy of the urethral muscular muscles thereby increasing mechanical pressure on the urethra, which in turn can prevent detrusor overactivity and prevent urinary incontinence.[37]

Several clinical studies have proven that the strength of PFM correlates with incontinence and that PFMT increases the strength of PFM can effectively speed up the recovery of incontinence in patients post radical prostatectomy.[17,38] In this study, we found that PFMT carried out before radical prostatectomy significantly reduced the risk of persistent urinary incontinence one month after radical prostatectomy [OR = 0.58 (95% CI, 0.41–0.81)], compared to patients who underwent PFMT only after surgery or did not undergo PFMT at all. This reduction in incontinence risk is consistent for up to 6 months postoperatively, in which most studies agree that the experimental group has a much higher rate of continence than the control group. At 12 months postoperatively, the control group could achieve the same continence rate as the experimental group, indicating that almost all patients in both groups had regained continence at 12 months postoperatively [OR = 1.31 (95% CI, 0.65–2.63)].

This meta-analysis combined several radical prostatectomy approaches, such as open radical prostatectomy (ORP), laparoscopic radical prostatectomy (LARP), and robot-assisted (RARP). A combination of these approaches was undertaken to increase the heterogeneity of studies extrapolated in various clinical settings. Moreover, several prospective comparative studies found no statistically significant difference in urinary incontinence between post-ORP, LRP, or RARP patients.[20,21]

Our findings are in line with Chang et al. (2016), who included six studies in their meta-analysis to determine the effect of PFMT in improving incontinence. The study found that the experimental group's odds were lower in 1, 3, and 6 months postoperatively and were significantly different in the three months postoperatively.[39] Some previous meta-analyses reported the opposite of what we found. Wang et al. (2014) reported no significant difference in the incidence of the relative risk of persistent incontinence at 1, 3, 6, and 12 months post radical prostatectomy.[40] However, this study included no more than four studies for meta-analysis, and there were only two studies that have good quality. A meta-analysis by Wu et al. (2019) found that guided-PFMT effectively reduced the risk of persistent incontinence at all time points, and preoperative guide-PFMT did not provide any benefit to patients. However, this study only included two studies and two-time points (3 and 6 months), and had a high heterogeneity (79%).[41]

The impact of incontinence on a patient's quality of life is clearly visible. Geraerts et al. (2013) reported a smaller reduction in quality of life in the preoperative exercise group, and all patients in the experimental group expressed satisfaction in receiving PFMT before surgery.[23] Research by Centemero et al. (2010) showed that 75% of patients in the intervention group reported a high level of satisfaction by starting PFMT before surgery.[18] Considering that urinary incontinence is a complication that significantly reduces the quality of life, any intervention that can shorten its duration is worth a try. Moreover, patients who receive additional PFMT before surgery show a high level of satisfaction, so PMFT can be a noninvasive therapy option that should be recommended to patients before radical prostatectomy.

There are several limitations in this meta-analysis that may interfere with the interpretation of final results. We found considerable heterogeneity between studies. This heterogeneity arises due to the large variety of PFMT regimens in each study. For example, PFMT accompanied and guided by a physiotherapist, accompanied by a biofeedback session, is the most widely used treatment regimen, but only 4 of 12 studies used this treatment regimen. One included study did not even include biofeedback in the treatment regimen. The definition of the "intervention group" in each study also varies. Three studies considered the intervention as an additional PFMT so that the treatment regimen between the control and experimental groups was the same, with the only difference being the time the therapy was started. Moreover, the definition of incontinence and continence of each study was also diverse, and it was impossible to establish a single definition of incontinence as an inclusion criterion. Some other things that cause high heterogeneity were surgery techniques, the frequency of PFMT intervention, and the time of initiation of preoperative and postoperative PFMT. Our meta-analysis included quite a large number of studies, and most had a low risk of bias, considering that participant blinding was not possible in this study with PICO.

CONCLUSIONS

PFMT initiated before radical prostatectomy significantly reduced the incidence of urinary incontinence in the first, third, and sixth months postoperatively. At 12 months postoperatively, additional preoperative PFMT did not cause a significant difference in the incidence of urinary incontinence.

CONFLICT OF INTEREST

The authors report no conflict of interest.

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