The therapeutic effect of pelvic floor muscle exercise on urinary incontinence after radical prostatectomy: a meta-analysis

Mei-Li-Yang Wu¹,², Cheng-Shuang Wang¹, Qi Xiao¹, Chao-Hua Peng¹, Tie-Ying Zeng¹

Pelvic floor muscle exercise (PFME) is the most common conservative management for urinary incontinence (UI) after radical prostatectomy (RP). However, whether the PFME guided by a therapist (G-PFME) can contribute to the recovery of urinary continence for patients after RP is still controversial. We performed this meta-analysis to investigate the effectiveness of G-PFME on UI after RP and to explore whether the additional preoperative G-PFME is superior to postoperative G-PFME alone. Literature search was conducted on Cochrane Library, Embase, Web of Science, and PubMed, to obtain all relevant randomized controlled trials published before March 1, 2018. Outcome data were pooled and analyzed with Review Manager 5.3 to compare the continence rates of G-PFME with control and to compare additional preoperative G-PFME with postoperative G-PFME. Twenty-two articles with 2647 patients were included. The continence rates of G-PFME were all superior to control at different follow-up time points, with the odds ratio (OR) (95% confidence interval [CI]) of 2.79 (1.53–5.07), 2.80 (1.87–4.19), 2.93 (1.19–7.22), 4.11 (2.24–7.55), and 2.41 (1.33–4.36) at 1 month, 3 months, 4 months, 6 months, and 12 months after surgery, respectively. However, there was no difference between additional preoperative G-PFME and postoperative G-PFME, with the OR (95% CI) of 1.70 (0.56–5.11) and 1.35 (0.41–4.40) at 1 month and 3 months after RP, respectively. G-PFME could improve the recovery of urinary continence at both early and long-term stages. Starting the PFME preoperatively might not produce extra benefits for patients at early stage, compared with postoperative PFME.

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Keywords: continence rate; pelvic floor muscle exercise; radical prostatectomy; urinary incontinence

INTRODUCTION

Prostate cancer is a common male cancer and a major cause of cancer-related death in men. It is estimated that nearly one-sixth of men will suffer from prostate cancer over a lifetime.¹ Radical prostatectomy (RP) is the most common therapy for prostate cancer.² However, RP may cause some bothersome complications, including the urinary incontinence (UI). The rates of UI after RP differed among various studies, and UI has been reported to happen in more than 80% patients 1 month after RP and 30% patients a year after RP.³,⁴ UI after RP immensely affects patients’ quality of life and leads to enormous economic burden for patients’ families. UI after RP results mainly from urethral sphincter deficiency or detrusor overactivity.⁵

Various therapeutic methods could be used to treat UI, including behavioral treatment, pharmacotherapy, and surgical therapy.⁶ Pelvic floor muscle exercise (PFME) is the most common conservative management for UI, which can improve the strength and endurance of striated muscles of the pelvic floor by repeated contractions, partially compensating the urethral sphincter insufficiency.⁷ PFME is thought to be an economical and safe therapy for patients.⁸ In order to correctly isolate and contract the pelvic floor muscles, patients usually need the guidance of a professional therapist. Moreover, with the guidance and encouragement of a therapist, patients can persist in the exercises for longer time to yield better results.⁹ A systematic review indicated that the compliance and adherence of patients were crucial for the efficacy of PFME. Thereby, an effective PFME should be under the guidance and supervision of a professional therapist.¹⁰ It was reported that postoperative PFME guided by a therapist (G-PFME) could hasten the recovery of urinary continence after RP.¹¹–¹³ However, several studies showed no beneficial effects of G-PFME, compared with only verbally instructed PFME (V-PFME) or no PFME.¹⁴–¹⁶ Whether G-PFME can contribute to the recovery of urinary continence for patients after RP is still controversial at present.

On the other hand, some investigators advocate starting the PFME preoperatively to help patients regain urinary continence. Although numerous studies showed positive results, others indicated that the additional preoperative PFME had limited benefits for patients after RP.¹⁷–¹⁹

We thereby performed this meta-analysis to investigate the effectiveness of G-PFME on UI after RP, and to explore whether the additional preoperative G-PFME is superior to postoperative G-PFME.
MATERIALS AND METHODS

Literature search
This meta-analysis was reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) and was registered at International Prospective Register of Systematic Reviews (registration number: CRD42018092219) (Supplementary Table 1).

A comprehensive literature search was conducted on Cochrane Library, Embase, Web of Science, and PubMed, to obtain all relevant English articles published before March 1, 2018. The search strategy was: (urinary incontinence) AND (radical prostatectomy) AND (pelvic floor) AND (randomiz*). Cited references of retrieved articles were also screened to gain extra publications. Studies from different databases were reviewed to exclude duplications. Two authors (MLYW and QX) participated in the literature searching process independently to avoid missing useful publications.

Inclusion criteria
Articles meeting the following criteria were included: (1) studies were randomized controlled trials (RCTs); (2) patients were diagnosed with prostate cancer and received RP; (3) the treatment group performed G-PFME while the control group received V-PFME or no PFME, or the treatment group began G-PFME preoperatively while the control group only performed postoperative G-PFME; (4) outcome was the number or percentage of patients regaining urinary continence. Studies with insufficient data were excluded.

Data extraction
The outcome characteristics of qualified studies were extracted, including the first author, year of publication, sample size, PFME regimens in both treatment group and control group, and follow-up time. The follow-up time was described as months after surgery. If there was more than one treatment group in a study, the patients’ number in the control group was divided equally according to the number of treatment groups.20 To ensure the accuracy and completeness, all data were extracted by two authors (CSW and QX) independently and any discrepancy between the two authors was resolved by discussion.

Quality of included studies
Quality of included studies was evaluated by the Cochrane Collaboration’s tool for assessing risk of bias. The tool consists of seven parts: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias. Each part can be graded as low risk of bias, unclear risk of bias, and high risk of bias (Supplementary Figure 1).

Statistical analyses
Outcome data were pooled and analyzed with the Review Manager (RevMan) Version 5.3 (The Nordic Cochrane Centre, the Cochrane Collaboration, Copenhagen, Denmark). As dichotomous data, the outcomes were presented as odds ratio (OR) with 95% confidence interval (CI) at different follow-up time points. Heterogeneity among studies was evaluated by the Q test, with Q > 50% considered to be of significant heterogeneity. In case of significant heterogeneity, random effects model was selected to analyze the outcome data and sensitivity analysis was performed to detect the source of heterogeneity, otherwise the fixed effects model was used. Intergroup difference was considered to be statistically significant when P < 0.05.

Based on the data we obtained from the qualified studies, we first compared the continence rates of G-PFME with V-PFME or no PFME at different follow-up time points. We defined both the V-PFME and no PFME as control in our study. Then, we compared additional preoperative G-PFME with postoperative G-PFME.

RESULTS

Eligible studies
Initially, 336 publications were searched from databases and other resources (Figure 1). After screening, 22 RCTs with 2647 patients were included in our study.11–19,21–33 All articles measured and compared the continence rates of patients in different groups, with the follow-up time ranging from 1 month to 1 year (Table 1). The definitions of continence were different among studies, with ten studies defining continence based on the number of pads used daily, eight based on the 24-h pad test, two based on bladder diary, and two based on the International Consultation on Incontinence Questionnaire on Urinary Incontinence (ICIQ-U1). Fifteen trials tested the effectiveness of postoperative G-PFME that started after catheter removal. The other seven trials investigated preoperative G-PFME beginning about 4 weeks before surgery and continuing after catheter removal, in which two trials compared preoperative G-PFME with postoperative G-PFME. The treatment regimen in different studies included G-PFME, G-PFME with biofeedback, and G-PFME combined with electrical stimulation. The control groups received no PFME or just V-PFME.

Quality of included studies
Altogether, most studies were of moderate-to-high quality according to the Cochrane Collaboration’s tool for assessing risk of bias (Figure 2). Fourteen studies performed the randomization with computer-generated random numbers, while the others did not explain the randomization methods. Moreover, nearly half of these studies concealed the allocation strategies. The treatment regimens in treatment group and control group were distinct; therefore, both the intervenors and patients were not blinded. However, the outcome assessors were blinded to the grouping and treatment in some trials. All studies conducted the follow-up investigations systematically and carefully and explained the reasons for dropout. No selective report existed in these trials. In addition, 12 studies calculated the sample size to increase the power of test.

Effectiveness of PFME on UI after RP
G-PFME could improve the recovery of urinary continence at both early (Figure 3) and long-term (Figure 4) stages. The follow-up time points were different among studies. We pooled and analyzed the
outcome data at 5 frequently used time points: 1 month, 3 months, 4 months, 6 months, and 12 months after surgery, separately. Ten articles measured the continence rate at the first month after surgery, showing that the OR between G-PFME group and control group was 2.79 (95% CI: 1.53–5.07; P = 0.0008). At 3 months, 4 months, and 6 months after the surgery, the ORs were 2.80 (95% CI: 1.87–4.19; P < 0.0001), 2.93 (95% CI: 1.19–7.22; P = 0.02), and 4.11 (95% CI: 2.24–7.55; P < 0.0001), respectively. After 1 year, the continence rate was still remarkably higher in G-PFME group, compared with control group, with the OR as 2.41 (95% CI: 1.33–4.36; P = 0.004).

We next explored whether additional preoperative G-PFME was better than postoperative G-PFME. Although there were seven articles investigating additional preoperative G-PFME, most of them compared preoperative G-PFME with postoperative V-PFME or no PFME. Only two studies set postoperative G-PFME as control group. We pooled data from these two articles and found that there was no apparent difference between additional preoperative G-PFME and postoperative G-PFME, with the OR as 1.70 (95% CI: 0.56–5.11; P = 0.35) and 1.35 (95% CI: 0.41–4.40; P = 0.62) at 1 month and 3 months after RP, respectively (Figure 5). However, this result was not so convincing due to the limited number of studies.

**DISCUSSION**

Our meta-analysis showed that G-PFME could hasten the recovery of urinary continence for patients after RP at both early and long-term stages. This suggested that G-PFME was an effective treatment strategy for UI and should be recommended to patients. A further analysis showed that, compared with postoperative G-PFME, starting the G-PFME before surgery did not bring remarkable extra benefits for patients. Whether patients should begin G-PFME preoperatively needs further research.

The mechanism of how PFME rescues UI is that repeated voluntary contraction of the pelvic floor muscles can enhance their strength and endurance. Several striated muscles can influence the urethral pressure, including the striated urethral rhabdosphincter, the bulbocavernous, and the levator ani muscle. Some verbal or written instructions were used to train patients to perform PFME, such as “elevate the penis,” “tighten the anus,” and “stop the uroflow.” These different verbal instructions lead to the contraction of different pelvic floor muscles. Because of the complexity of the anatomy of pelvic floor muscles, it is difficult for patients to judge which muscle is contracted and whether the contraction is correct. Moreover, avoiding the contraction of abdominal muscles during PFME is also a challenge for patients. Thereby, an effective PFME need the guidance of a professional therapist who can teach patients correct exercises with digital anal palpation or biofeedback devices. Transabdominal real-time ultrasound imaging could also be used to visualize the structures of pelvic floor and help patients isolate muscle activation. No matter which...
guidance method was used, the purpose of G-PFME was to achieve correct and effective muscle contraction. Moreover, the guidance and supervision of a therapist can help patients to keep on performing the exercise. On the contrary, the PFME with only verbal/written instructions was thought to be useless and was treated as control group in most studies.

Before conducting PFME, a therapist should explain the anatomy and function of pelvic floor muscles to patients. Then patients are trained to contract the pelvic floor muscles correctly. After that, patients are requested to conduct the PFME daily at different positions, including supine position, sitting, standing, and squatting. Patients are also encouraged to practice PFME before activities which may induce leakage of urine, such as coughing, sneezing and lifting heavy things. In addition, patients need to pay a return visit to the therapist at regular intervals to adjust exercise methods.

PFME could decrease the incontinent episodes in older women and men with stress and urge incontinence. Some studies also showed that PFME were effective for UI after RP. Glazener et al. reported that the UI rate was not apparently different between the intervention group receiving a four-session G-PFME and control group with standard care. Their
explanation was that the information about PFME was widely available and patients in the control group might also have conducted the PFME by themselves. Similarly, a study by Dubbelman et al. showed that G-PFME had no beneficial effect on the regain of continence. The authors attributed the negative results to insufficient sample size. Bales et al. thought that a more frequent and intensive PFME program would produce a better outcome. Our meta-analysis collected all the available RCTs in regard to PFME and UI after RP up to date, in order to obtain more compelling evidence. Our result verified that G-PFME was an effective and lasting strategy for UI after RP, because the continence rate was higher in G-PFME group than that in control group at 1 month, 3 months, 4 months, 6 months, and 12 months after surgery.
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To improve the efficacy of PFME, some researchers attempted to train patients to conduct PFME preoperatively. Burgio et al.15 pointed out that initiating PFME preoperatively could make patients more prepared for the exercise. Besides, patients could learn how to contract the pelvic floor muscles with full sensation and without pain if they started the PFME preoperatively. Their study indicated that preoperative PFME could hasten the regain of continence and reduce the severity of UI. Chang and colleagues16 conducted a meta-analysis to evaluate the effect of additional preoperative PFME on postprostatectomy UI, demonstrating that preoperative PFME improved the early but not long-term continence rates. Since both preoperative PFME and postoperative PFME were reported to be beneficial in some studies, which one should be chosen for patients? Centemero et al.17 reported that preoperative PFME could improve early recovery of continence compared with postoperative PFME. On the contrary, a study by Geraerts et al.18 indicated that starting PFME before surgery did not produce better results than starting PFME after catheter removal. Therefore, we performed the meta-analysis to resolve this disagreement. After pooling data from two studies, we found that additional preoperative PFME did not hasten the recovery of continence at 1 month and 3 months after RP, compared with postoperative PFME. However, this finding should be interpreted cautiously due to the limited number of studies. Furthermore, as the preoperative PFME in these two studies began 3 or 4 weeks before the surgery, it was not clear whether starting the PFME more early would produce better results. Further investigations were essential to resolve this issue.

Our meta-analysis included enough studies and most studies had low risk of bias. Nevertheless, the study is limited by the heterogeneity of included studies, which was caused by multiple factors. First of all, the type of treatment regimens varied among studies, including the way to guide PFME (palpation, biofeedback devices, or ultrasound), the frequency of PFME, and the length of PFME. In addition, the definition of continence differed between trials, such as pad free, no leakage based on bladder diary, and no more than 4 g urine on 24-h pad test. These differences were inevitable as there is no standard treatment regimen and precise definition of continence at present. Sensitivity analysis was conducted by removing the included studies one by one to detect the source of heterogeneity. However, no study was found to be responsible for the heterogeneity. Thereby, we could only perform our meta-analysis with the random effect model to reduce the influence of heterogeneity.

CONCLUSIONS

This meta-analysis demonstrates that G-PFME could hasten the recovery of UI after RP at both early and long-term stages. We thereby recommend G-PFME to patients after RP to regain continence early. Starting the PFME 1 month before the surgery might have no extra benefits compared with postoperative PFME. However, this result requires further investigations.

AUTHOR CONTRIBUTIONS

MLYW and QX searched and selected studies, CSW and QX extracted and analyzed the data. MLYW and TYZ drafted the manuscript. MLYW, CHP, and TYZ revised the manuscript. All authors read and approved the final manuscript.

COMPETING INTERESTS

All authors declared no competing interests.

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Supplementary Information is linked to the online version of the paper on the Asian Journal of Andrology website.

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### Supplementary Figure 1: Risk of bias summary

| Study             | Random sequence generation (selection bias) | Allocation concealment (selection bias) | Blinding of participants and personnel (performance bias) | Blinding of outcome assessment (detection bias) | Incomplete outcome data (attrition bias) | Selective reporting (reporting bias) | Other bias |
|------------------|--------------------------------------------|----------------------------------------|----------------------------------------------------------|-----------------------------------------------|----------------------------------------|-----------------------------------|------------|
| Ahmed 2011       | +                                          | +                                      | ?                                                        | +                                             | ?                                      | +                                 | ?          |
| Aylin 2018       | ?                                          | ?                                      | ?                                                        | +                                             | ?                                      | +                                 | ?          |
| Bales 2000       | ?                                          | ?                                      | +                                                        | +                                             | ?                                      | +                                 | ?          |
| Burgio 2006      | +                                          | +                                      | +                                                        | +                                             | ?                                      | +                                 | ?          |
| Centemero 2010   | +                                          | +                                      | ?                                                        | +                                             | +                                      | +                                 | ?          |
| Dubbelman 2010   | +                                          | +                                      | ?                                                        | ?                                             | +                                      | +                                 | ?          |
| Eshuis 2013      | +                                          | +                                      | +                                                        | +                                             | ?                                      | +                                 | ?          |
| Filocamo 2005    | ?                                          | ?                                      | ?                                                        | +                                             | +                                      | +                                 | ?          |
| Franke 2000      | ?                                          | ?                                      | ?                                                        | ?                                             | +                                      | +                                 | ?          |
| Geraerts 2013    | +                                          | +                                      | +                                                        | +                                             | +                                      | +                                 | ?          |
| Glazener 2011    | +                                          | ?                                      | ?                                                        | +                                             | +                                      | +                                 | ?          |
| Kampen 2000      | +                                          | +                                      | ?                                                        | +                                             | +                                      | +                                 | ?          |
| Manassero 2007   | +                                          | ?                                      | ?                                                        | +                                             | +                                      | +                                 | ?          |
| Marchiori 2010   | ?                                          | ?                                      | ?                                                        | +                                             | +                                      | +                                 | ?          |
| Mariotti 2009    | ?                                          | ?                                      | ?                                                        | +                                             | +                                      | +                                 | ?          |
| Moore 2008       | +                                          | +                                      | ?                                                        | +                                             | ?                                      | +                                 | ?          |
| Overgard 2008    | +                                          | ?                                      | ?                                                        | +                                             | +                                      | +                                 | ?          |
| Parekh 2003      | ?                                          | ?                                      | ?                                                        | +                                             | ?                                      | +                                 | ?          |
| Pedriali 2015    | +                                          | +                                      | ?                                                        | +                                             | +                                      | +                                 | ?          |
| Ribeiro 2010     | +                                          | ?                                      | ?                                                        | +                                             | +                                      | +                                 | ?          |
| Tienforti 2012   | +                                          | ?                                      | ?                                                        | +                                             | +                                      | +                                 | ?          |
| Yamanishi 2010   | +                                          | +                                      | ?                                                        | +                                             | +                                      | +                                 | ?          |
### Supplementary Table 1: Preferred Reporting Items for Systematic Reviews and Meta-Analyses checklist

| Section/topic          | # | Checklist item                                                                                           | Reported on page # |
|------------------------|---|----------------------------------------------------------------------------------------------------------|-------------------|
| Title                  |   | Title                                                                                                    |                   |
| Abstract               |   | Structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number | 1                 |
| Introduction           |   | Rationale                                                                                                 | 1                 |
|                        |   | Objectives                                                                                                 | 1                 |
| Methods                |   | Protocol and registration                                                                                   | 2                 |
|                        |   | Eligibility criteria                                                                                      | 2                 |
|                        |   | Information sources                                                                                       | 2                 |
|                        |   | Search                                                                                                    | 2                 |
|                        |   | Study selection                                                                                           | 2                 |
|                        |   | Data collection process                                                                                   | 2                 |
|                        |   | Data items                                                                                                 | 2                 |
|                        |   | Risk of bias in individual studies                                                                         | 2                 |
|                        |   | Summary measures                                                                                          | 2                 |
|                        |   | Synthesis of results                                                                                      | 2                 |
|                        |   | Risk of bias across studies                                                                               | NA                |
|                        |   | Additional analyses                                                                                       | NA                |
| Results                |   | Study selection                                                                                           | 2                 |
|                        |   | Risk of bias within studies                                                                               | 2, 3              |
|                        |   | Results of individual studies                                                                             | 2, 3              |
|                        |   | Synthesis of results                                                                                      | 2, 5              |
|                        |   | Risk of bias across studies                                                                               | 2-5               |
|                        |   | Additional analysis                                                                                        | NA                |
| Discussion             |   | Summary of evidence                                                                                        | 3-6               |
|                        |   | Limitations                                                                                               | 6                 |
|                        |   | Conclusions                                                                                               | 6                 |
| Funding                |   | Funding                                                                                                   | 6                 |

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*Note: The table continues with additional rows for each section, detailing specific checklist items and their reported pages.*