

Penile Rehabilitation Therapy Following Radical Prostatectomy: A Meta-Analysis



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ABSTRACT

Background: Penile rehabilitation, defined as the use of any drug or device at or after radical prostatectomy to maximize erectile function recovery, is commonly used for post-prostatectomy erectile dysfunction; however, conflicting results based on each study make it difficult to give a recommendation for clinical practice.

Aim: To clarify the effect of oral phosphodiesterase type 5 inhibitors (PDE5is), vacuum erection devices, intracorporeal injection therapy, and the combination of these treatments on penile rehabilitation.

Methods: A comprehensive publication search was done through the PubMed and Embase databases up to February 8, 2017. The reference lists of the retrieved studies also were investigated. Data were analyzed using STATA 12.0. A fixed- or random-effects model was used to calculate the overall combined odds ratio (OR) or standard mean differences (SMDs). Publication bias was assessed using the Begg and Egger tests.

Outcomes: Change in sexual function before and after treatment.

Results: After screening, 11 randomized controlled trials and 5 case-control studies were included. The overall meta-analysis showed that penile rehabilitation with PDE5is, vacuum erection devices, and intracorporeal injection significantly increased the number of patients with erectile function improvement (OR = 2.800, 95% CI = 1.932–4.059, $P = .000$) and International Index of Erectile Function (IIEF) score (SMD = 5.896, 95% CI = 4.032–7.760, $P = .000$). In subgroup analysis based on study design, randomized controlled trials and case-control studies showed that penile rehabilitation increased the number of patients with erectile function improvement (randomized controlled trials: OR = 2.154, 95% CI = 1.600–2.895, $P = .000$; case-control studies: OR = 2.800, 95% CI = 1.932–4.059, $P = .000$). Subgroup analysis for PDE5i treatment also only demonstrated an increased patient response rate (OR = 2.161, 95% CI = 1.675–2.788, $P = .000$) and IIEF scores (SMD = 0.922, 95% CI = 0.545–1.300, $P = .000$). However, after PDE5i washout, there was no improvement of spontaneous erectile function (OR = 1.027, 95% CI = 0.713–1.478, $P = .610$).

Clinical Translation: This study provides information about the efficacy of penile rehabilitation that can help clinicians decide treatment strategies.

Strengths and Limitations: This meta-analysis has higher statistical power than each study. Preoperative patient characteristics, various treatment methods, and different follow-up times might bring bias to pooled effects.

Conclusion: Our meta-analysis confirmed that administration of PDE5is, vacuum erection devices, and intracorporeal injection after radical prostatectomy can increase erection function during treatments. However, current evidence does not support that penile rehabilitation with PDE5is can improve recovery of spontaneous erectile function. Further studies with adequate follow-up and larger samples should be conducted to generate a comprehensive conclusion. **Liu C, Lopez DS, Chen M, Wang R. Penile Rehabilitation Therapy Following Radical Prostatectomy: A Meta-Analysis. J Sex Med 2017;14:1496–1503.**

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Key Words: Rehabilitation; Radical Prostatectomy; Erectile Dysfunction; Meta-Analysis

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INTRODUCTION

Prostate cancer, one of the most common cancers in men, has been responsible for 161,360 new cases and 26,730 deaths in Americans in 2017.¹ Prostate-specific antigen testing allows prostate cancer to be diagnosed at a lower disease stage.² For early localized prostate cancer, radical prostatectomy (RP) is the most commonly used first-line treatment.³ Although many advances have been made in understanding prostate anatomy and the use of minimally invasive technology, erectile dysfunction (ED) after RP remains a common adverse effect negatively affecting patients' quality of life.⁴ ED after RP is mainly attributed to neurovascular bundle trauma and this cannot be completely avoided even with the best nerve-sparing techniques.⁵ The neurovascular bundle will be affected by mechanical manipulation, heating, ischemic effects, and local inflammation.⁶ The reported incidence rates of ED after RP range from 6% to 68%.⁷

Erectile function can return gradually after surgery, although it can take approximately 2 years or longer.⁸ Only few patients will return to their baseline erectile function.⁹ Because of this, penile rehabilitation was proposed to stimulate recovery of erectile function after RP. The concepts of penile rehabilitation can be defined as the use of any drug or device at or after RP to maximize erectile function recovery. Although there are different treatment methods used in penile rehabilitation, the most common approaches of penile rehabilitation after RP are oral phosphodiesterase type 5 inhibitors (PDE5is), vacuum erection devices (VEDs), intracorporeal injection (ICI) therapy, and a combination of these treatments.¹⁰ Unfortunately, conflicting results based on each study make it difficult to give a recommendation for clinical practice. Therefore, we conducted a quantitative meta-analysis to clarify the effect of these treatments on penile rehabilitation.

METHODS

Search Strategy

We performed a comprehensive publication search through the PubMed and Embase databases up to February 8, 2017, with no language limit. The following terms were used: "radical prostatectomy AND erectile function AND rehabilitation OR recovery." References cited in retrieved articles and reviews also were scanned to identify relevant publications.

Study Selection

Studies included in this meta-analysis satisfied the following criteria: (i) a study that included post-RP ED; (ii) a study that included the effect of scheduled PDE5is, ICI, VED, and combinations of these treatments; (iii) a study whose full text and sufficient data could be accessed; and (iv) the language must be English. The main exclusion criteria were (i) reviews, editorial comments, background, animal models, and case reports; (ii) insufficient data; (iii) a duplicated study or study that used a

sample more than once; and (iv) studies with PDE5i use as needed.

Data Extraction

To ensure objectivity, all articles were independently reviewed by 2 investigators. Discrepancies were resolved by consensus. From each study, the following information was extracted: first author's name, year of publication, study population, duration of follow-up, treatment methods, assessment tools, and outcomes.

Statistical Analysis

Statistical analyses were conducted using STATA 12.0 (StataCorp, College Station, TX, USA). To evaluate the effect of penile rehabilitation, odds ratio (OR) and 95% CI were used for 2-category data and standard mean difference (SMD) and 95% CI were used for continuous data. For heterogeneity among studies, the I^2 test was used. If the data did not have significant heterogeneity ($I^2 < 50\%$), then the OR and SMD were analyzed by the fixed-effect model. If the data had heterogeneity, then they were analyzed by the random-effect model. Sensitivity analyses were performed by sequentially removing each eligible study. Publication bias was determined by the Begg funnel plot and the Egger test. Subgroup analysis was performed when there were enough data to identify the source of heterogeneity.

RESULTS

Study Characteristics

The initial search found 623 articles in PubMed and 971 articles in Embase. After applying additional filters, 16 studies involving 2,012 patients were included in this review.^{11–26} Figure 1 presents the detailed process of selecting and excluding studies. These studies were performed by different medical centers in different countries. Almost all patients received nerve-sparing surgery. The most commonly used treatment was PDE5is.^{12,16–26} The follow-up time was 12 weeks to 24 months. Of the 16 studies, 11 were randomized controlled trials (RCTs) and the remaining 5 were case-control studies (Table 1). The International Index of Erectile Function (IIEF) was the most commonly used assessment tool for erectile function evaluation. Almost all studies provided the rehabilitation rate or number and some studies provided the IIEF score before and after treatment. Because some studies provided only 1 type of data, the meta-analysis was done twice with different types of data. In the PDE5i group, some studies contained the outcomes after drug washout, so meta-analysis was applied to those data individually. Most data were obtained directly but some data were obtained by calculation.

Penile Rehabilitation and Erectile Function

The overall meta-analysis showed that penile rehabilitation with PDE5i, VED, and ICI significantly increased the number of the patients with erectile function improvement (OR = 2.800,

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