

Efficacy of pelvic floor muscle training on the sexual function of men after radical prostatectomy: an overview of systematic reviews

Eficácia do treinamento muscular do assoalho pélvico na função sexual dos homens após a prostatectomia radical: uma visão geral das revisões sistemáticas

Eficacia del entrenamiento muscular del piso pélvico sobre la función sexual en hombres después de una prostatectomía radical: una descripción general de las revisiones sistemáticas

Received: 07/29/2022 | Reviewed: 08/09/2022 | Accept: 08/11/2022 | Published: 08/21/2022

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Abstract

This study aimed to evaluate the evidence in the literature on the efficacy of pelvic floor muscle training on the sexual function (SF) of men after prostatectomy by an overview of systematic reviews (SR) of randomized clinical trials. The search for studies was conducted in five databases without any language restriction: EMBASE, PUBMED, Science Direct, PEDro, and Cochrane Library. The main results were extracted from the SR by two reviewers, and meta-analysis was performed from the primary studies for the outcomes SF scores and erectile dysfunction. 4 reviews were included in the qualitative synthesis, which involved 8 clinical trials and 891 participants. The reviews had moderate to good methodological quality, but a high overlap of clinical studies was founded. Meta-analysis showed that pelvic floor muscle training improves sexual function scores not in 3 months ($p=0.51$) but in 6 months ($p=0.02$) and it did not show efficacy on erectile dysfunction after three ($p=0.58$) and 12 months ($p=0.32$). Studies with moderate to good methodological quality demonstrate that pelvic floor muscle training only improve sexual function score in 6 months, but not had efficacy in erectile dysfunction in men after prostatectomy.

Keywords: Prostatectomy; Erectile dysfunction; Rehabilitation; Pelvic floor disorders, male.

Resumo

Este estudo teve como objetivo avaliar as evidências na literatura sobre a eficácia do treinamento muscular do assoalho pélvico na função sexual (FS) de homens após prostatectomia por meio de uma revisão sistemática (RS) de ensaios clínicos randomizados. A busca dos estudos foi realizada em cinco bases de dados sem restrição de idioma: EMBASE, PUBMED, Science Direct, PEDro e Cochrane Library. Os principais resultados foram extraídos da RS por dois revisores, e a metanálise foi realizada a partir dos estudos primários para os desfechos escores SF e disfunção erétil. Quatro revisões foram incluídas na síntese qualitativa, que envolveu 8 ensaios clínicos e 891 participantes. As revisões tiveram qualidade metodológica de moderada a boa, mas foi encontrada uma alta sobreposição de estudos clínicos. A meta-análise mostrou que o treinamento da musculatura do assoalho pélvico melhora os escores da função sexual não em 3 meses ($p=0,51$), mas em 6 meses ($p=0,02$) e não mostrou eficácia na disfunção erétil após três ($p=0,58$) e 12 meses ($p=0,32$). Estudos com qualidade metodológica de moderada a boa demonstram que o treinamento da musculatura do assoalho pélvico apenas melhora o escore da função sexual em 6 meses, mas não teve eficácia na disfunção erétil em homens após a prostatectomia.

Palavras-chave: Prostatectomia; Disfunção erétil; Reabilitação; Distúrbios do assoalho pélvico masculino.

Resumen

Este estudio tuvo como objetivo evaluar la evidencia en la literatura sobre la efectividad del entrenamiento de los músculos del piso pélvico en la función sexual (FS) en hombres después de la prostatectomía a través de una revisión sistemática (RS) de ensayos controlados aleatorios. La búsqueda de estudios se realizó en cinco bases de datos sin

restricciones de idioma: EMBASE, PUBMED, Science Direct, PEDro y Cochrane Library. Dos revisores extrajeron los resultados principales del RS, y el metanálisis se realizó a partir de los estudios primarios para las puntuaciones de SF y los resultados de disfunción eréctil. Se incluyeron 4 revisiones en la síntesis cualitativa, que involucró 8 ensayos clínicos y 891 participantes. Las revisiones fueron de calidad metodológica moderada a buena, pero se encontró una alta superposición de estudios clínicos. El metanálisis mostró que el entrenamiento de los músculos del suelo pélvico mejora las puntuaciones de la función sexual no a los 3 meses ($p=0,51$) sino a los 6 meses ($p=0,02$) y no mostró eficacia en la disfunción eréctil después de tres ($p=0,58$) y 12 meses ($p=0,32$). Los estudios con una calidad metodológica moderada a buena demuestran que el entrenamiento de los músculos del suelo pélvico solo mejora la puntuación de la función sexual a los 6 meses, pero no tiene eficacia en la disfunción eréctil en los hombres después de la prostatectomía.

Palabras clave: Prostatectomía; Disfunción eréctil; Rehabilitación; Trastornos del suelo pélvico masculino.

1. Introduction

Prostate cancer is the sixth cause of death in men, with a worldwide incidence of up to 1.3 million and being the fourth most common malignancy in the world (Bray et al., 2018). Despite the clinical complications and advances in surgical procedures, radical prostatectomy yet is the most common treatment for prostatic cancer (Barakat et al., 2021; Heidenreich et al., 2015).

Surgical treatment for radical prostatectomy is commonly associated with complications, including adverse effects on sexual function (Jarzemski et al., 2019). The most common symptoms are erectile dysfunction, difficulty with achieving orgasm, penis deformity or shortening, fertility changes, and decreased sexual desire. These changes precede psychological function problems in these patients. since these complications are related to the patient's masculinity (Jarzemski et al., 2019).

The literature includes different therapies to minimise sexual function disorders and improve the quality of life of these patients. Therapy with prostaglandin and phosphodiesterase-5 inhibitors as well as pelvic floor muscle training (PFMT) have shown good results in the management of these dysfunctions (Geraerts et al., 2016). PFMT has been increasingly touted as the first-line treatment for voiding dysfunction after prostatectomy, providing better periurethral support of the pelvic floor muscles in cases of climacturia and erectile dysfunction (Geraerts et al., 2016).

In recent years, clinical studies have been developed to evaluate the efficacy of PFMT in improving the sexual function of post-prostatectomy patients. Systematic reviews were develop previously to assess the level of evidence of this treatment (Perez et al., 2018) (de Lira et al., 2019; Oh et al., 2020), but they have important methodological limitations that need to be considered, since they include studies that are not randomised clinical trials (RCT) or not assess directly DE as an outcome.

Thus, the present overview aims to identify and evaluate the quality of the available evidence on the use of PFMT in improving the sexual function of men after prostatectomy. Therefore, it is expected to provide evidence to clinicians and researchers about the real efficacy of this type of treatment alone. The research question of this overview is: How effective is PFMT (intervention) in improving the sexual function (outcome) of men post radical prostatectomy (population)?

2. Methodology

2.1 Study design

This overview of systematic reviews was conducted following the Preferred Reporting Items for Overviews of Reviews and the Preferred Reporting Items for OoSRs (PRIO-harms and PRIO for abstracts) (Bougioukas et al., 2019; Bougioukas et al., 2018). This overview was registered in PROSPERO under protocol number CRD42020221381.

2.2 Inclusion and exclusion criteria

SR with or without RCT meta-analyses on the effect of PFMT on the sexual function of men after prostatectomy were included in this overview, with no restrictions on age, sample size, date, language, or place of treatment. PFMT was defined as pelvic floor muscle rehabilitation protocols through pelvic floor muscle strengthening exercises, which were either associated with biofeedback and electrostimulation or not (P. W. Hodges et al., 2019).

Reviews that evaluated other forms of interventions or other interventions associated with PFMT, as well as those that did not assess the quality of evidence of primary studies, were excluded.

The primary outcomes of this overview were sexual function evaluated by self-reports or the International Index of Erectile Function (IIEF) (Rosen et al., 1999), total scores and domains.

2.3 Study search and selection strategy

Identified and eligible reviews were selected using a search strategy in the following databases: MEDLINE via PubMed (Medical Literature Analysis and Retrieval System Online/PubMed), COCHRANE LIBRARY (Cochrane Central Register of Controlled Trials), SCIENCEDIRECT, Embase, and PEDro (Physiotherapy Evidence database).

The searches were conducted on January 15, 2022 and involved a combination of different terms chosen from the guiding question using the Boolean operators AND OR. The strategy search used was: (male OR man OR men OR prostatectomy OR prostate adenectomy OR prostate resection OR radical prostatectomy OR total prostatectomy) AND (PFMT OR Kegel exercise OR pelvic floor exercise) AND (sexual dysfunction OR impotence OR erectile dysfunction OR male sexual dysfunction) AND (systematic review OR review, systematic OR systematic review). No language or year of publication restriction were applied. Then, we included any review published until January 2022.

The records found were exported to Mendeley software and duplicate entries were removed. Two independent reviewers screened the studies by reading the title and abstract, and then the full text. In case of disagreements, a third reviewer was consulted for consensus as to the inclusion of the study in the overview. The Kappa coefficient assessed the agreement between the reviewers in the process and was interpreted as moderate ($k = 0.41 - 0.60$), substantial ($k = 0.61 - 0.80$), or near perfect agreement ($k \geq 0.81$) according to Gilchrist (2008) (Gilchrist, 2009).

2.4 Data extraction

The data were extracted using a specific form containing data on the year of publication, authors, objectives, and eligibility criteria, RCT number and characteristics (population, intervention and control protocols, time of assessment, duration of follow-up, outcomes, results presented), assessment of methodological quality, and risk of bias. Whenever necessary, the researchers searched the primary study for missing or divergent information. Data extraction and methodological quality assessment were independently performed by two reviewers.

2.5 Methodological quality assessment

The methodological quality of the reviews analysed was assessed using the Assessment of Multiple Systematic Reviews (AMSTAR) tool, which aims to identify and describe the quality of SR, evaluating biases, possible conflicts of interest, and study results (Shea et al., 2017). Each tool item assesses whether the review meets the criteria, and yes, no, or not applicable can be selected.

The quality of the evidence was assessed using the Grades of Recommendation, Assessment, Development and Evaluation (GRADE) (Schünemann et al., 2013) system.

Corrected covered area (CCA) was used as a measure of RCT overlap (Pieper, Antoine, Mathes, Neugebauer, & Eikermann, 2014). It is an appropriate way to assess the overlap of primary studies in overviews, which, through a repetition and publication index, results in a possible range between 0 and 100%. A CCA value lower than five can be considered as a slight overlap, whereas values greater than or equal to 15 can be considered as a remarkably high overlap (Pieper et al., 2014). The calculation to verify the degree of overlap through the area covered and corrected area covered considered the number (n) of studies, reviews, and duplicates found.

Meta-analyses were recreated from the raw data of the primary studies to estimate the magnitude of the treatment effect more accurately. The meta-analysis was conducted using RevMAN 5.3 (Cochrane Collaboration, London, UK). Odds ratios and 95% confidence intervals were calculated for dichotomous outcomes and mean differences, while only 95% confidence intervals were calculated for continuous outcomes. The fixed or random effect model was used for calculation depending on the degree of heterogeneity evidenced in each analysis. The effect was considered significant when p-value was <0.05.

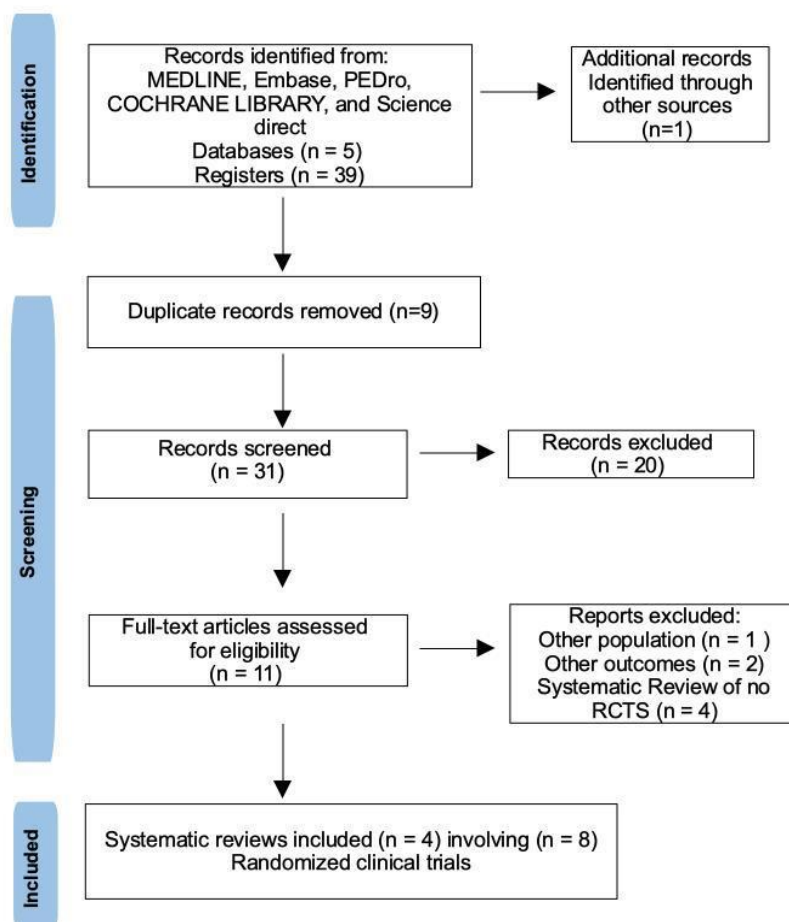
3. Results

The search for studies identified 39 articles, and only 4 SR were included. A total of 8 RCT and 891 participants were included. A flowchart describing the screening and included studies is shown in Figure 1. In the screening process, the Kappa coefficient showed almost perfect agreement between reviewers ($k = 0.90$).

Three SR included in this overview showed good methodological quality and two study presenting moderate methodological quality, as shown in Table 1.

The overlap of studies is presented through a citation matrix in Table 2. It shows that 62% of the articles were included in at least two reviews. The reviews included in this overview showed a high overlap of the included RCTs, demonstrated by the high values of CA (53%) and CCA (37%).

Figure 1. Flowchart of systematic review.



Source: Own elaboration.

Table 1: Methodological quality assessment of reviews included using the AMSTAR tool.

Systematic Review	Methodological quality	Number and % of items covered	Items not covered	Items nuclear or not applicable
(Kannan et al., 2019)	High	13/16 (81%)	Item 9, 10, and 14.	n/a
(Feng et al., 2020)	High	13/16 (81%)	Item 2, 4, and 10.	n/a
(Wong, Louie, & Beach, 2020)	High	12/16 (75%)	Item 10	Item 11, 12, and 15.
(Nicolai, Urkmez, Sarikaya, Fode, & Falcone, 2021)	Medium	6/16 (37%)	Item 3, 5, 7, 9, 10, 13 and 14.	Item 11, 12, and 15.

Note: The numbering of items used in the table follows the same numbering as in the AmSTAR tool (Shea et al., 2017).
 Source: Own elaboration.

Different PFMT parameters were analysed in this overview: the number of sessions used, duration and instruction provided by the therapist, description of the training and the training progression regimen used, the professional who administered the training, the resources used, in this case if biofeedback was used, striated muscle coordination, and the clear description of the training for the patient to perform at home, considering the principles of a PFMT (P. Hodges et al., 2019). The findings regarding the parameters found in each review are shown in Table 3 and 4.

Table 2: Citation matrix of randomized clinical trials in the systematic reviews included.

Randomized clinical trials	(Kannan et al., 2019)	(Feng et al., 2020)	(Wong et al., 2020)	(Nicolai et al., 2021)
(Geraerts et al., 2016)	Included	Included	Included	-
(Laurienzo et al., 2018)	-	Included	Included	-
(Lin, Yu, Lin, Wang, & Lu, 2012)	Included	Included	Included	-
(Prota et al., 2012)	Included	Included	Included	-
(Oh et al., 2020)	-	Included	-	-
(de Lira et al., 2019)	-	Included	-	-
(Glazener et al., 2011)	Included	Included	Included	-
(Miliotis, Ackland, & Green, 2020)	-	-	-	Included

Source: Own elaboration.

Table 3. Evaluated protocol parameters.

Variables	(Kannan et al., 2019)	(Feng et al., 2020)	(Wong et al., 2020)	(Nicolai et al., 2021)
PICO anatomy	What is the efficacy of physiotherapy interventions compared to controls in improving EF and climacturia after radical prostatectomy (PR) or transurethral resection (TUR)?	What is the effect of medication, supportive therapy, or device therapy compared with different interventions on EF and adverse effects in postoperative ED patients?	In men undergoing PR, does PFMT improve EF alone or in combination with other treatment techniques?	Not reported
Language restrictions	no	no	Yes	Yes
No. of RCT with PFMT included in the overview	7	8	7	1
Total No. of studies included in the review	7	38	9	24
Number of participants	1.622	897	826	97
Age (years)	47 - 90	mean 63	Not reported	Mean 62-63
No. of sessions	n	Yes	no	Yes
Description of the duration of the intervention	Yes	Yes	Yes	Yes
Verbal instruction for PFM contraction	no	n	no	No
PFMT description	Yes	Yes	Yes	Yes
There was periodisation	no	no	no	no
Professional who performed the intervention	Yes	Yes	Yes	no
Biofeedback use	Yes	Yes	Yes	no
Checked PFM coordination	no	no	no	no
Objective prescription for PFMT at home	Yes	Yes	Yes	no
Results founded	There is limited and low-quality evidence regarding the success of PFMT for EF.	Evidence on the use of PFMT on short- and long-term SF outcomes is conflicting.	High-quality studies have conflicting results on the use of PFMT in ED.	PFMT did not show statistically significant differences between groups.

Source: Own elaboration.

Table 4. Characteristics of the RCTs included in the reviews.

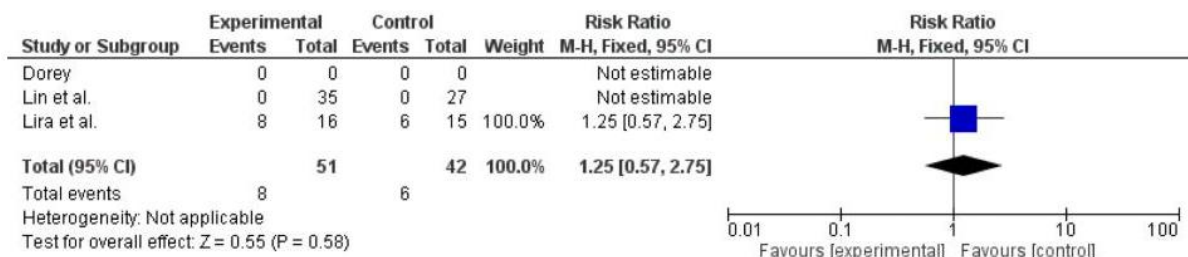
RCT's	(Geraerts et al., 2016)	(Laurienzo et al., 2018)	(Glazener et al., 2011)	(Lin et al., 2012)	(Prota et al., 2012)	(Oh et al., 2020)	(de Lira et al., 2019)	(Milios et al., 2020)
Total no. of participants (IG/CG)	33 (16/17)	123 (41**/42***/40)	411 (205/206)	62 (35/27)	52	82 (40/42)	31 (16/15)	97 (50/47)
Ages of participants (IG/CG)	61,1 and 61,5*	58,5 ± 5.4/58,0 ± 5.7	62.4 ± 5.8/62.3 ± 5.6	65.75*	62.4 ± 6.4/64.0 ± 8.0	67.5 ± 6.9/65.9 ± 6.8	63.53 ± 7.62/67.3 ± 5.63	62,2±6,8/63,5±6,8
Intervention	IG: Therapist-guided PFMT and ES for 10 min (symmetrical biphasic current), intensity as high as possible, non-painful, frequency: 50 Hz and pulse duration: 600 µ s. CG: no treatment.	IG1: PFMT in dorsal decubitus with lower limb flexion, pelvic floor contraction. IG2: PFMT and ES twice a week for 7 weeks, totalling 14 sessions. CG: no treatment.	IG: PFMT guided by a physical therapist. 3 CVM of 10 s, 2x a day in several outlets. Oriented to perform contraction during sex. CG: no treatment	IG: PFMT + BF. CG: No treatment in the first three months.	IG: Physical therapist led PFMT using BF and anal electromyography (EMG), 3 10 rapid contractions and three sustained contractions. CG: programme at home.	IG: PFMT and BF four times a day; 10 min per exercise session; CG: a minimum of 10 seconds of maximum tension intensity. CG: PFMT.	IG: PFMT+ BF (EMG) guided by physiotherapist, pre-PR sessions, return after removal of urethral catheter. CG: only usual care after PR.	GC: Usual pelvic floor muscle training of 3 sets/d GI/GC: High intensity pelvic muscle training of 6 sets/d pelvic floor muscle training in standing, both groups.
Follow-up	3 months	3 and 6 months	3, 6 and 12 months	3, 6, 9 and 12 months	3, 6 and 12 months	3 months	3 months	No follow-up during treatment.
Outcome measurements	IIEF-EF, VAS	IIEF-5.	Self-report by patients and shown "Number of men unable to achieve Any erection 12 months after prostate surgery."	IIEF-5.	IIEF-5.	IIEF-5.	IIEF-5; ICIQ-SF	IIEF-5; EPIC-CP
Results	In 15 months, IG obtained a better EF score than CG. IG: (4.1 - 5.6) CG: (0.2 - 2.4). By IIEF-EF treatment effect was maintained in both groups during and at the end of the treatment (p = 0.925).	TMAP versus no treatment, short term showed no significant differences in the assessment of EF through the IIEF-5. Each group had a significant score improvement at 6 months.	It was not possible to observe evidence of difference between the groups of trial on the effect on faecal incontinence or erectile function	There were significant differences between IG and CG at 6 and 12 months. 6 months, IG: 6.34, CG: 5.00 and 12 months, IG: 8.14, CG: 5.96	There was an acute reduction in IIEF-5 scores in both groups after treatment; however, there was a considerable improvement in IG at 12 months (47.1%) compared to CG (12.5%).	There were no scale differences preoperatively and at 1, 2, and 3 months postoperatively regarding total IIEF-5 score changes.	There was no scale improvement with PFMT and BF compared to CG (no treatment or usual care) at 3 - 6 months.	No statistically significant differences between the two groups on any outcome measure.

IG = Intervention group; CG = Control group; PFMT = Pelvic floor muscle training; PR = prostatectomy; EF = erectile function; FS = sexual function; IIEF = International Index of Erectile Function; CVM = maximal voluntary contraction; BF = biofeedback; EMG = electromyography; PVS = penile vibratory stimulation. *Mean; **IG1; ***IG2. Source: Own elaboration.

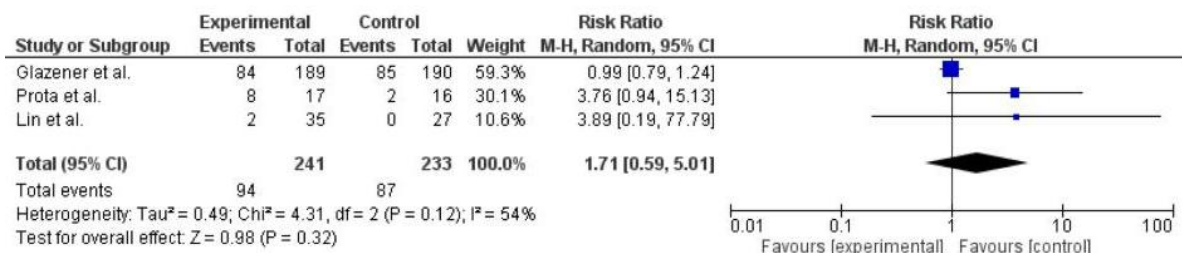
Meta-analyses were performed comparing primary studies regarding the efficacy of PFMT for erectile dysfunction (ED) and sexual dysfunction (SF), as shown in Figure 2. Total International Index of Erectile Function (IIFE) score increased six months after PFMT ($p = 0.02$). PFMT showed no efficacy on ED after three ($p = 0.58$) and 12 months ($p = 0.32$), as well it did not improve the total IIFE score after three months ($p = 0.51$). According to the GRADE, PFMT has a low degree of recommendation for ED and SD. Despite we included 9 RCT on this overview, only RCTs that assess the ED with the same tool and time were pooled on the forest plot.

Figure 2. Efficacy of pelvic floor muscle training on erectile dysfunction and sexual function. (a) Efficacy of PFMT in ED after 3 months, (b) Efficacy of PFMT in ED after 12 months, (C) Efficacy of PFMT in the IIFE scores after 3 months, (d) Efficacy of PFMT in the IIFE scores after 6 months. PFMT: pelvic floor muscle training; ED = erectile dysfunction. IIFE: International Index of Erectile Function.

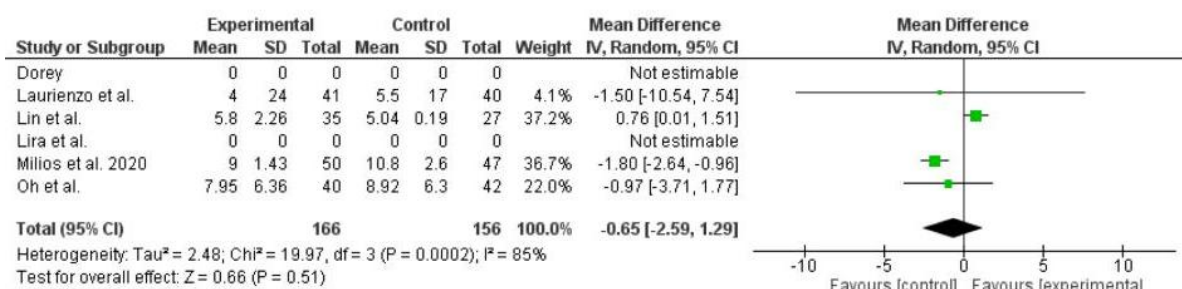
(a) Efficacy of PFMT in ED after 3 months



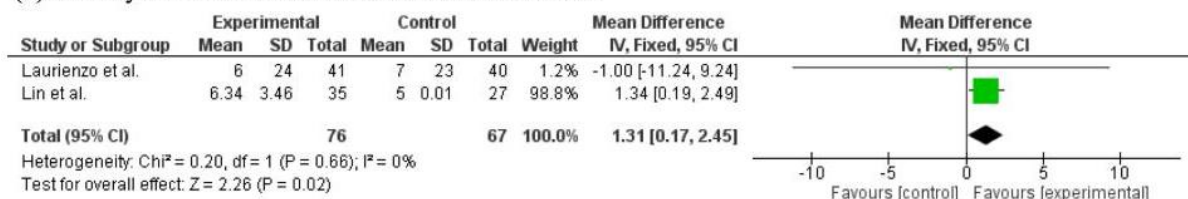
(b) Efficacy of PFMT in ED after 12 months



(C) Efficacy of PFMT in the IIFE scores after 3 months



(d) Efficacy of PFMT in the IIFE scores after 6 months



Source: Own elaboration.

4. Discussion

ED and SF are constant complaints in patients, undergoing prostate removal, and among the treatments, PFMT seems promising for use in clinical practice in improving sexual function after surgery (Geraerts et al., 2016; Kannan et al., 2019). However, most studies show both dysfunctions as secondary outcomes, thus creating a gap regarding the use of PFMT. In contrast to these promising results, this overview of current evidence shows that there is only a low level of recommendation for the use of PFMT to treat SD in men post-prostatectomy, since PFMT is associated with higher IIFE scores six months after the intervention but has no effect on the percentage of men with erectile function (EF). Meta-analysis performed shows that the interpretation of effect size differs from the clinical trial conclusions, which in general favour PFMT alone or a combination of biofeedback or electrostimulation in SD and ED after prostatectomy. Such findings respond more clearly to the gap left in the reviews by Wong et al.⁵; Feng et al.⁷ and Kannan et al.¹⁶, which report conflicting evidence on the effect of PFMT on SD.

The overlap rate evaluates the repetition of the primary studies and their findings present in the SR (Pieper et al., 2014). The high rate verified in this overview points to the need for new clinical trials and shows that new SR should only be conducted when new evidence emerges or becomes outdated.

The training used in the analysed studies was performed after catheter removal (de Lira et al., 2019), and PFMT was performed alone or with biofeedback pressure and electromyography, electrical stimulation (ES), and guidance by a physical therapist (de Lira et al., 2019; Geraerts et al., 2016; Glazener et al., 2011; Laurienzo et al., 2018; Oh et al., 2020; Prota et al., 2012).

However, with regards to this context, there is an important gap concerning the use of PFMT for these patients, considering that the intervention protocols are not clear and have great divergences, such as the parameters to be used with biofeedback (BF) and ES, training protocol with number of sessions and repetitions, adequate guidance for continuity in the home environment, as well as the patient's adherence to the proposed treatment. According to a previous study (P. W. Hodges et al., 2019), PFMT personalisation should be based on the basic principles of motor learning and exercise physiology, considering the patient's individuality and thus ensuring satisfactory contraction as well as greater understanding and control of the proposed training.

Reconsiderations on the pelvic rehabilitation of post-prostatectomy patients demonstrate that the target muscle, treatment regimen, command, and guidance provided to the patient can influence PFMT, since the contraction mechanisms must aim to activate adequate contraction of muscles in the male patient; for example, puborectalis and bulbocavernosus muscle contraction to increase striated sphincter strength to improve the efficacy of training for urinary incontinence, since the studies included or developed up to now often use old female rehabilitation reasoning, which involve different muscular mechanisms from continence maintenance. Considering this reasoning, PFMT for sexual function may be promising in these patients, since the muscles related to continence are also involved in ED and SD maintenance.

Perhaps the conflicting results from systematic reviews analysed can be explained by the variation in the duration and characteristics of the intervention protocols used. Considering that there is evidence that erectile function in men may require a time of 18 to 24 months to be re-established or to show improvement (Andrew R McCullough, 2005), it may be questioned whether the intervention time in these patients does not need to be longer, as well as the follow-up time.

Finally, as a limitation of this overview, we highlight the impossibility of conducting more robust meta-analyses, due to the variability of evaluation methods and presentation of outcomes and results in publications. As well, the short follow-up time performed by the studies to document improvements in ED outcomes.

In this sense, it is recommended that new studies use internationally validated and accepted measures to measure outcomes and have a longer follow-up period for these patients. In addition, it is suggested the use of good practices for the

development of clinical trials and description of interventions, allowing the production of a better level of evidence on the subject and facilitating the process of transposing evidence into clinical practice.

5. Conclusion

Although the SR included in this overview showed moderate to good methodological quality, they presented high overlap rates and contradictory conclusions. When recomposing the meta-analyses, the PFMT only show efficacy to increase the IIFE scores in 6 months ($p=0.02$). on the other hand, PFMT did not demonstrate efficacy in the number of patients with erectile dysfunction. This fact may suggest that the erectile function recovery process requires longer treatment and follow-up.

It should be noted that most of the intervention protocols analysed were not specifically designed for SD and have flaws regarding the measurement of outcomes and training administration.

According to the GRADE, PFMT has a low degree of recommendation for ED and SD. New studies with high methodology quality and using the new insights on pelvic rehabilitation in men are recommended to produce new evidence on the clinical applications of PFMT in these patients.

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