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Systematic Review

Electrical Muscle Stimulation for the Conservative Management of Female Pelvic Floor Muscle Dysfunction: A Scoping Review

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Abstract

Background: Electrical muscle stimulation (EMS) is a conservative management tool for the treatment of pelvic floor dysfunctions (PFDs). The aim of this review was to scope, summarize and critically evaluate available research investigating the impact of various modes of EMS on PFDs in females. **Methods**: Joanna Briggs Institute methodology for scoping reviews was used with The Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews. Three databases were searched. Articles published in English that included female participants living with pelvic floor muscle dysfunction where EMS was used as a conservation care intervention were included in the review. Included studies were analyzed following Arksey and O'Malley's framework. The Cochrane Risk of Bias Tool for randomized trials was used to assess risk of bias for the randomized controlled trials (RCTs), and Hawker and Payne's quality appraisal criteria was used to appraise the data from the other included papers systematically. **Results**: A total of 37 studies, including 20 RCTs were included. A favorable impact, across various outcomes, was found across trials which investigated different types of EMS with varying protocols. The heterogenous nature of intervention protocols limited the ability to apply any statistical or meta-analyses. EMS demonstrates a positive effect for improving outcomes related to PFDs in adult women. Included studies support the use of EMS for stress, urgency and mixed urinary incontinence. All versions of EMS studied were found to provide significant improvements, which included them being used as a sole intervention or as an adjunct intervention. High intensity forms of EMS were consistently found to require shorter intervention times. **Conclusions**: EMS demonstrates improvement across outcomes for PFDs among adult women. In particular, the results of this review suggest that EMS may be particularly useful in women living with stress urinary incontinence (SUI) or who those are unable to perform voluntary muscle contractions when pelvic floor muscle training is attempted. Further research related to more novel versions of high intensity EMS approaches is needed.

Keywords: review; pelvic floor disorders; female; electric stimulation therapy; conservative treatment

1. Introduction

Electrical muscle stimulation (EMS) is a conservative management tool for the treatment of pelvic floor dysfunctions (PFDs; e.g., bladder and bowel incontinence, pelvic pain, dyspareunia, sexual dysfunction, and pelvic organ prolapse [POP]) that is supported by the 7th International Consultation on Incontinence (ICI) from the International Continence Society (ICS) and the International Consultation on Urological Diseases (ICUD) [1]. The 2023 *Incontinence* recommendations indicate that EMS can be considered for treatment to improve symptoms of urgency urinary incontinence (UUI), and that it can improve quality of life in women living with stress urinary incontinence (SUI; grade of recommendations: B). According to the 2023 *Incontinence* recommendations, medical treatments (e.g., vaginal oestrogens, propantheline bromide, and oxybutynin) appear to be less effective than EMS, or a combination of pelvic floor muscle training (PFMT) and EMS, for SUI (grade: B) [1]. Further, evidence suggests that magnetic EMS (i.e., EMS in conjunction with a magnetic field that depolarizes membranes of peripheral motor neurons and initiates muscle contraction at what are considered greater intensities than non-magnetic EMS and has been referred to as causing "supramaximal" muscle contraction) [2] should be considered for improving symptoms in women living with mixed urinary incontinence (MUI) and SUI (grade: B-new when compared to no active treatment) [1].

Pelvic floor dysfunction (PFD) is a term used to describe a series of clinical diagnoses that include challenges with control of bladder and bowel function such as incontinence, pelvic pain, dyspareunia, sexual dysfunction, and POP [3,4]. Pelvic health physical therapy (PHPT) and PFMT are conservative, first-line treatments for many pelvic floor disorders (level of evidence: 1) [1,5,6]. PFMT is a general term for the instruction of pelvic muscle strengthening, relaxation, and coordination exercises led by a trained physical therapist [7]. PHPT, denotes the conglomerate of care provided by pelvic health physiotherapists which includes; education, lifestyle and behavioural counseling, manual therapy, exercise prescription, including PFMT and the use of adjuncts to support the delivery of PFMT [8–10]. Robust evidence supports the role of PHPT as a first line, minimally invasive option to treat PFDs [1,11–13].

In the treatment of PFDs, EMS modalities can be used to promote muscle contractions through depolarization of the motor units in muscle tissue. EMS modalities have been used in the management of PFD, specifically urinary incontinence, for decades [14]. A wide variety of EMS tools that vary in design, application, invasiveness, and treatment parameters currently exist. Some EMS tools are designed to be used intra-vaginally, which have been reported to sometimes cause adverse events such as discomfort [5], while others apply the energy externally to the perineal region [15,16]. Studies have shown that a significant percentage of women with diagnosed PFDs struggle with voluntary pelvic floor muscle contractions [17,18]. In one study of 325 women presenting for evaluation of a diagnosed PFD, only 23% were able to perform a contraction with Oxford Scale strength $\geq$3/5 [17]. In other study of 239 incontinent women, approximately 70% were unable to perform a voluntary pelvic floor muscle contraction [18]. EMS has; therefore, been suggested to provide significant benefit to rehabilitation of pelvic musculature, especially for people with muscle weakness or who are unable to perform voluntary muscle contractions [19], in addition it has been thought to be a useful addition to standard PFMF in order to achieve a higher overall therapeutic dose [1].

A recent systematic review [20] examining perspectives on the therapeutic effects of pelvic floor EMS highlights the positive effects of EMS on urinary control and sexual quality but acknowledges clear gaps in the literature regarding EMS intensity, frequency, and duration. The results highlight a lack of standardization for EMS treatment. Current research does not provide evidence about outcomes based on the use of specific EMS tools, procedures, and protocols. In addition, newer EMS tools have been developed in recent years, many of which can only be accessed in a clinic environment. These innovations of EMS claim to be more advantageous than traditional tools, but the currently such comparisons have yet to be found in the existing literature. Therefore, the aim of this review is to scope, summarize and critically evaluate available research investigating the impact of all current forms of EMS on PFDs in females.

2. Materials and Methods

A scoping review allows the mapping of key concepts underpinning a research area and is useful when a topic has yet to be comprehensively reviewed. A five-stage methodological framework was used to guide the review according to the following steps: (1) identify the research question; (2) identify relevant studies; (3) select studies for more-detailed analysis; (4) chart the data; and (5) collate, summarize and report the results [21,22]. Joanna Briggs Institute methodology was also applied to supplement the scoping review methodology [23,24]. The review protocol was registered on the Open Science Framework on November 28, 2022 (https://osf.io/nt58u) and followed Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. As a scoping review, ethical approval was not required in order to research.

2.1 Inclusion and Exclusion Criteria

The inclusion and exclusion criteria are presented in the methods summary (Table 1).

2.2 Search Strategy

Computer-aided searches of MEDLINE (Ovid), EMBASE (Ovid), and CINAHL were conducted in collaboration with a Health Sciences Librarian at McMaster University, who suggested the above three databases to ensure literature saturation. The final search was conducted in September 2022 (Table 1). All search terms were searched as keywords in addition to each database's specific subject headings (e.g., MEDLINE). Within each database, search terms for *electrical stimulation*, *electromagnetic*, *pelvic*, *pelvic floor*, and *women* were included (see **Supplementary File 1**). No restrictions on language of publication were included in the search (i.e., language was used as an inclusion criterion that was manually confirmed by study authors), but databases were filtered to display results from the year 2017 and onwards only.

2.3 Study Selection

Covidence review management software was used for study screening and selection (https://www.covidence.org/). Citations identified through our database search were uploaded into Covidence, where duplicates were removed. Two authors [PA, NG] screened the identified papers against our inclusion criteria. Additional insight from other study authors was obtained when necessary to resolve concerns about literature eligibility. *A priori* it was determined that disagreements would be resolved through discussion; however, no disagreements about study inclusion occurred.

2.4 Data Extraction

All authors performed full text data extraction to identify information from each paper (see **Supplementary File 2**). Arksey and O'Malley (2005) [21] framework was followed for the analysis of extracted data.

Table 1. Inclusion and exclusion criteria of studies for review.

Key search teams	Pelvis, pelvic floor, electrical stimulation, electrical stimulation therapy, high frequency electrical simulation, electromagnetic simulation.
Sampling strategy	Selective databases: from medicine, nursing, allied health, and science fields within specified limits. Journal hand searching from reference lists.
Type of article	All original, peer reviewed quantitative studies (randomized controlled trials, quasi experimental, cross sectional and cohort studies)*.
Approaches	Citation searches, cross referenced with google scholar and contact with authors – 38 searches including combination of search terms completed.
Language	English.
Range of years	January 2017–December 2023.
Inclusion and exclusion	Inclusion: studies with female subjects (18 years and older) with the diagnosis or self-reported clinical presentation of PFDs (e.g., FI, POP, and/or impaired sexual function), studies that evaluated EMS as the intervention, studies that included conservative care interventions as the comparison or control group, studies that had at least one clear measurable outcomes measure that was physical assessment or self-report. Excluded: studies on populations other than the above, studies that used energy based modalities that did not incorporate an EMS component, studies that did not report clearly enough on intervention parameters or outcome measures, studies that used pharmacological or surgical interventions as the comparison, studies that used EMS for assessment not an intervention, and studies published prior to January 2017 and in a language other than English.
Electronic sources	Medical Literature Analysis and Retrieval System Online (MEDLINE), Excerpta Medica Database (EMBASE), and Cumulative Index of Nursing and Allied Health Literature (CINAHL). Hand searching and reference list searching were also employed to locate peer-reviewed literature.

PFD, pelvic floor dysfunction; FI, fecal incontinence; POP, pelvic organ prolapse; EMS, electrical muscle stimulation. All types of study designs were considered for inclusion.

*Published abstracts of studies meeting the inclusion criteria were included. Articles not available in English or that were strictly theoretical, conceptual, or grey literature were excluded.

2.5 Quality Appraisal and Risk of Bias

One author [PA] individually assessed the quality of the non-randomized trials using Hawker *et al*. (2002) [25] quality appraisal criteria. The Hawker *et al*. (2002) [25] tool consists of nine subscales (i.e., abstract and title, introduction and aims, method and data, sampling, data analysis, ethics and biases, results, transferability and generalizability, and implications and usefulness of the study). The items in each subscale are rated on a 4-point ordinal scale described as good (4), fair (3), poor (2), and very poor (1). Each article received a summary score within a range of 9–36 [25]. A score of 28–36 was associated with good quality articles, 20–27 for fair articles, 10–20 for poor quality articles, and less than 10 for very poor-quality articles.

A different author [HA] independently assessed the risk of bias for the included randomized trials using the Cochrane Risk of Bias Tool for randomized trials (RoB 2) [26]. The risk of bias (RoB) 2 assesses seven domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data (attrition bias), selective reporting (reporting bias), and other biases [26]. Risk was categorized as: low, high or unclear with some concerns.

3. Results

A total of 37 articles from 15 different countries published between 2017–2022 were included in this review (Fig. 1). All studies demonstrated improvements on outcomes following the studied EMS intervention (Table 2, Ref. [8,14–16,27–58]).

3.1 Study Characteristics

Of the 37 studies, the majority were randomized controlled trials (RCTs) (n = 20), followed by prospective cohort studies (n = 13), with the remaining 4 studies constituting low level designs; retrospective (n = 3) and pilot (n = 1). Refer to Table 2 for a summary of results.

3.2 Methodological Quality of the Included Studies

The 20 RCTs were rated using the Cochrane RoB 2. Fourteen of the studies were found to have low risk of bias, and six of the studies were found to have some concerns regarding risk of bias (Fig. 2 and Table 2). The other 17 studies were assessed for quality using the Hawker & Payne scale. Twelve of the studies were rated as “good” quality, three were rated as “fair”, one was rated “poor,” and one was rated “very-poor” (Table 2). Overall, the majority of the risk of bias assessments for the included RCTs was low, and the quality assessments for the prospective and retrospective studies (including the one pilot study) was high, indicating we can have reasonable trust in the results of this review; however, we suggest interpreting each included study with caution as appropriate based off their individual assessments (Table 2).

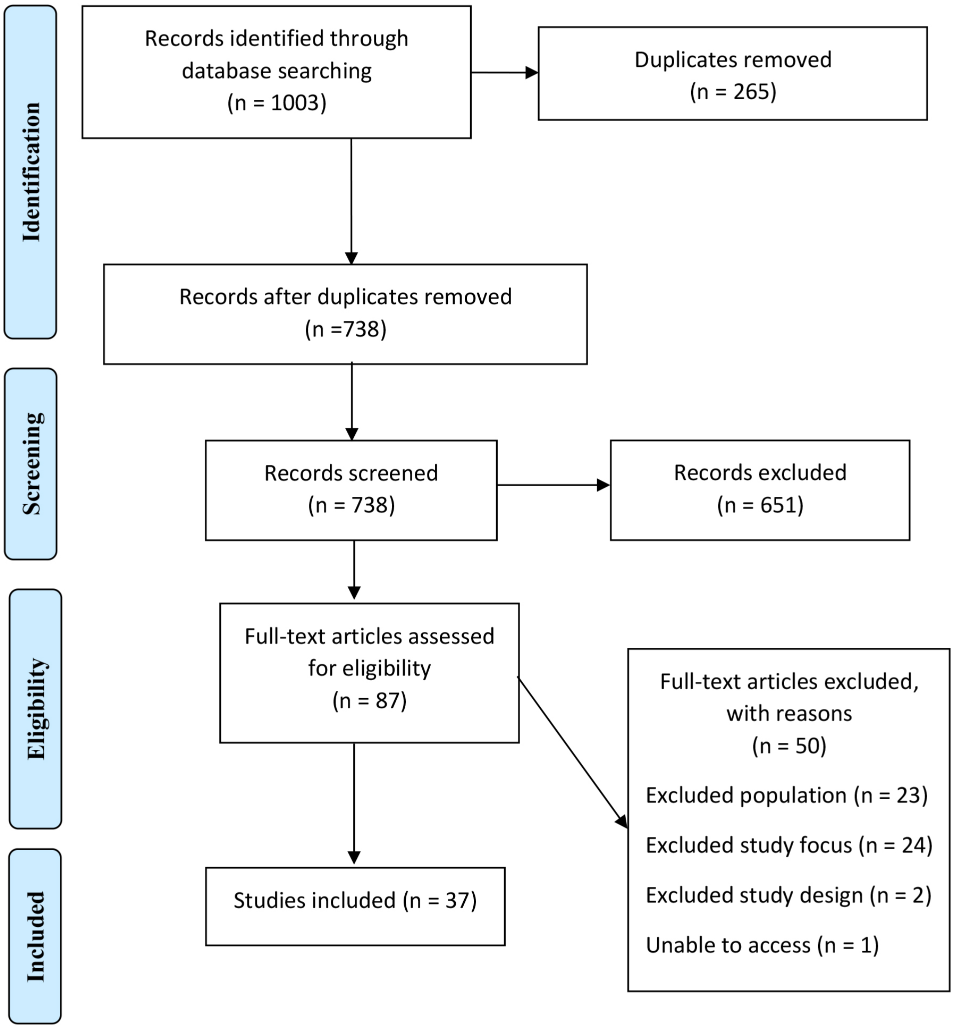

Fig. 1. Flow-chart of the process of the scoping review article identification, screening, and eligibility.

3.3 Participant Characteristics

All but one study included only female participants (n = 36; see Table 2). Additionally, the majority of studies included participants in perimenopause or menopause (n = 34). Only four studies used EMS interventions for women in the postpartum period. Eleven studies specifically focused on females with SUI (Table 2). Six other studies included females with any type of UI. Two studies included people living with POP. People living with fecal incontinence (FI) were included in five studies. Five studies focused on overactive bladder (OAB) patients while the remaining seven studies included participants living with any lower urinary tract symptoms (LUTS), FI and/or sexual dysfunction (e.g., dyspareunia). Most studies used outcomes measures that captured PFDs outside of the condition that was used for study recruitment. As such PFDs was determined to encompass a variety of systems and conditions across studies beyond that of the diagnosis used as part of the primary inclusion, highlighting the multifaceted nature of PFD.

3.4 Types of EMS

The majority of studies used traditional intra-vaginal or intra-rectal probes as the mode of EMS induction (n = 20; see Table 2). As for as more novel versions of EMS, N = 15 studies used tools that applied EMS externally. Of these, N = 11 used high frequency electromagnetic stimulation (HIFEM), with N = 6 via the Emsella ($<$10 kHz), N = 1 used the Pelvipower (50 Hz), N = 1 FMS Tesla Care (50–60 Hz), N = 1 Smart Kegel (27 Hz), N = 1 Neo Control Chair (50 Hz), and N = 1 Solus Talen devices (50 Hz). HIFEM technology was the most studied option that applied EMS externally. Only four studies that used externally delivered EMS used a low-frequency, all four studies used the same device, EasyK7 (25 Hz). Two studies did not report whether the EMS used was external versus internal.

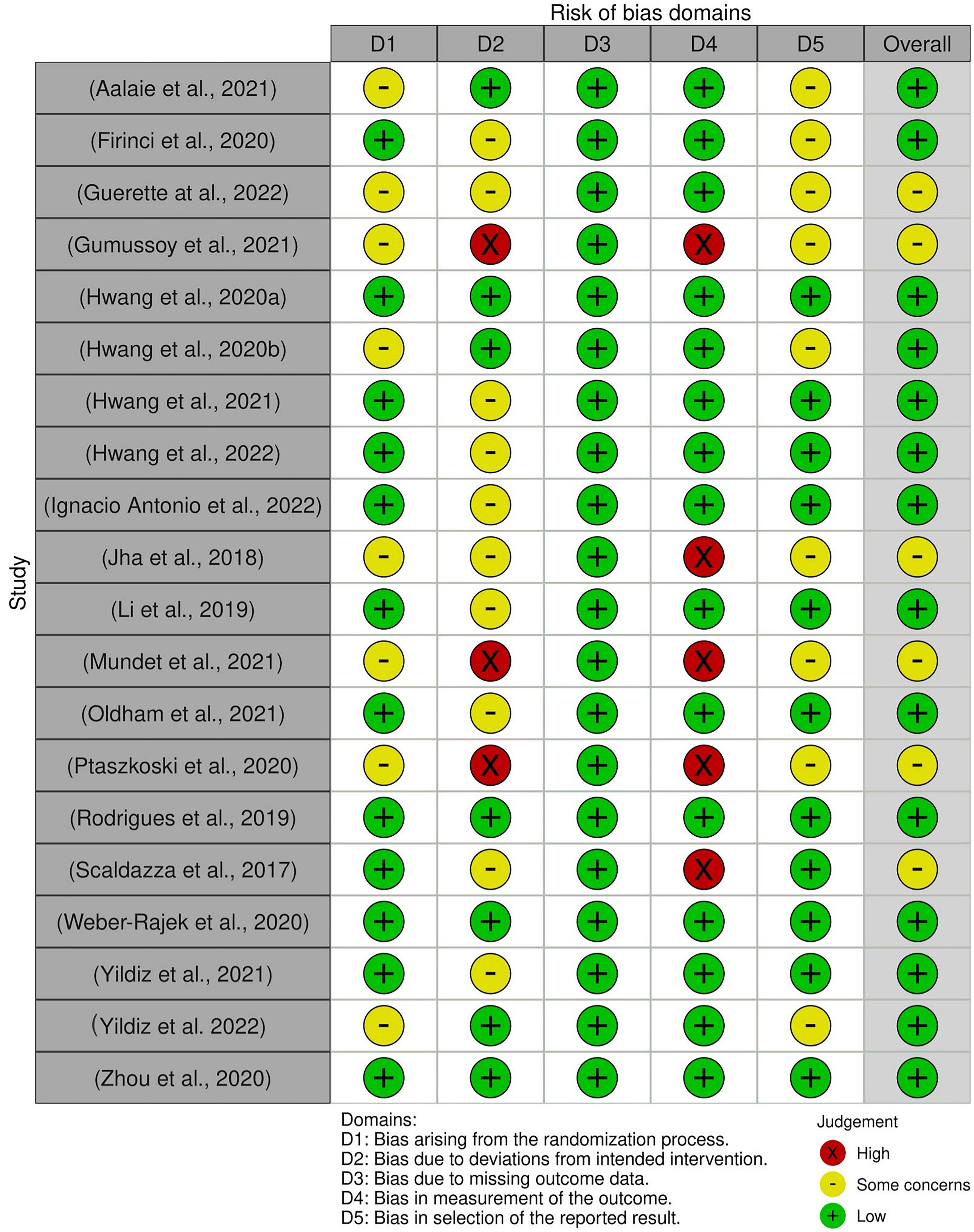

Fig. 2. Risk of Bias Assessment for included randomized controlled trials (RCTs) in the review.

Table 2. Description of reviewed studies.

Author/country	Study design	Sample size	Participants (median age, years)	EMS type; mode; Tool used	Intervention parameters	Outcome measures	Relevant findings	Risk of bias/quality assessment
Aalaie *et al.*, 2021 Iran [30]	RCT	22	Women (50.1)	Low frequency (10 Hz); intervaginal; Enraf Nonius Myomed	2 sessions/w 6 w 100 min/session Total = 1200 min	FSFI	Significant improvement on FSFI score ($p < 0.05$) with both EMS and biofeedback interventions. Biofeedback was superior to EMS for improving multiple domains of sexual function	Low risk of bias
Brusciano *et al.*, 2020 Italty [31]	Prospective cohort	30	Women, n = 26 Men, n = 4 (65)	High frequency (60 Hz); HIFEM external application; Tesla Care®Armchair	1 session/w 8 w 15 min/session Total = 120 min	CCFIS FIQL	Significant improvement of the CCFIS and FIQL ($p < 0.05$)	Score = 30 Good quality
Chiu *et al.*, 2018 USA [32]	Retrospective case series	27	Women (49.7)	Low frequency (20 Hz); intravaginal; Urostym®	Ranged across participants Minimum of 4 sessions to fulfil the intervention criteria = 21/27	Number of urinary incontinence accidents	Significant decrease in the number of urinary incontinence accidents post EMS intervention ($p < 0.001$)	Score = 25 Fair quality
Firinci *et al.*, 2020 Turkey [33]	RCT	69	Women (55)	Low frequency (10 Hz); intervaginal; Enraf Nonius Myomed	3 sessions/w 8 w 20 min/session Total = 480 min	Pad test (24 h) PFM strength IIQ-7	Adding EMS to behavioral therapy increased treatment effectiveness on all outcomes	Low risk of bias
Guerette 2022 USA [15]	RCT	47	Women (43)	High frequency (>10 kHz); HIFEM external application; Emsella	2 sessions/w 3 w 28 min/session Total = 168 min	Pad use (over 6 months) UDI-6 ICIQ-LUTS	Significant improvements in ICIQ-LUTS in the HIFEM group ($p < 0.001$), but not the PFMT group, which was maintained at 12-months ($p < 0.05$) Other outcomes improved in both groups	Some risk of bias concerns
Gumussoy *et al.*, 2021 Turkey [34]	RCT	51	Women (51)	High frequency (50 Hz); HIFEM external application; Magther E-6000 system	2 sessions/w 8 w 20 min/session Total = 320 min	Pad test (1 h) I-QOL FSFI PFMS (perineometry and oxford scale)	The mean scores on the I-QOL improved significantly in both groups ($p < 0.001$), FSFI scores significantly improved ($p < 0.001$), and pad weight significantly decreased ($p < 0.001$) There was no statistically significant difference between the groups in terms of cure and improvement ($p = 0.895$)	Some risk of bias concerns

Table 2. Continued.

Author/country	Study design	Sample size	Participants (median age, years)	EMS type; mode; Tool used	Intervention parameters	Outcome measures	Relevant findings	Risk of bias/quality assessment
Hiemstra *et al.*, 2020 Netherlands [35]	Pilot study abstract only	31	Women	High frequency (50 Hz); HIFEM external application; Pelvipower	1 session/w 6 w 30 min/session Total = 180 min	PGI-S PGI-I	33% of participants (n = 5) went from mild/moderate SUI complaints to light/no complaints on the PGI-S and PGII. The number of participants with moderate to severe SUI decreased from 62% to 40%	Score = 16 Poor quality
Hwang *et al.*, 2020 Korea [36]	RCT	34	Women (42)	Low frequency (25 Hz); external application; EasyK7	5 sessions/w 8 w 15 min/session Total = 600 min	PFMS (perineometry) UDI-6 Pad test (ultra short)	Significant differences were observed in the EMS group for muscle strength, power and endurance ($p < 0.05$), UDI-6 score ($p < 0.05$) and pad weight ($p < 0.05$) when compared to the control group. We found that increased PFM power (among the various muscle functions) reduced subjective and objective symptoms after 8 weeks of surface electrical stimulation	Low risk of bias
Hwang *et al.*, 2020 Korea [37]	RCT	33	Women (42)	Low frequency (25 Hz); external application; EasyK7	5 sessions/w 8 w 15 min/session Total = 600 min	PFMS (perineometry) PSIQ	The *p*-values for the differences in PFM measurements between the groups, and between the pre and post-intervention measurements within the EMS group, were 0.001 and 0.004 for power, 0.015 and 0.011 for strength. In addition, in the PISQ increased to a greater extent in the EMS group	Low risk of bias
Hwang and Lee 2021 Korea [16]	RCT	33	Women (42)	Low frequency (25 Hz); external application; EasyK7	5 sessions/w 8 w 15 min/session Total = 600 min	PFMS (perineometry) Diaphragm excursion (ultrasound)	There were significant differences for a main effect between pre- and post-training and between groups in PFM strength in favour of the EMS group. PFM strength ($p < 0.001$) was significantly increased after 8 weeks in the EMS group	Low risk of bias

Table 2. Continued.

Author/country	Study design	Sample size	Participants (median age, years)	EMS type; mode; Tool used	Intervention parameters	Outcome measures	Relevant findings	Risk of bias/quality assessment
Hwang *et al.*, 2023 Korea [38]	RCT	34	Women (42)	Low frequency (25 Hz); external application; EasyK7	5 sessions/w 8 w 15 min/session Total 600 min	IIQ-7 PISQ PFMS (perineometry)	The EMS group showed significantly improved IIQ-7 scores and PFM performance, and had significantly higher values in both one and double-leg lowering tests ($p < 0.05$) after 8 weeks of training, indicating significant improvement from pre-session values ($p < 0.005$)	Low risk of bias
Ignácio Antônio *et al.*, 2022 Brazil [8]	RCT	61	Women (53)	High frequency (50 Hz); intravaginal; device not specified	1 session/w 8 w 20 min/session	PFMS (oxford scale) ICIQ-UI-SF	PFMS was acquired by 36% of the experimental group and 12% of the control group (absolute risk difference 0.24, 95% CI: 0.02 to 0.43). The experimental group improved by a mean of 2 points more than control group on the ICIQ-UI-SF (95% CI: 0.02 to 3.97)	Low risk of bias
Jha *et al.*, 2018 England [39]	RCT	144	Women (46)	Low frequency (40 Hz); intervaginal; device not specified	EMS protocol not reported	PISQ SF-36	No significant differences in outcomes between groups. Both groups demonstrated clinical significant improvement	Some risk of bias concerns
Kołodyńska *et al.*, 2022 Poland [40]	Prospective cohort	60	Women (57)	Low frequency (20 Hz); intervaginal; MyoPlus4	5 sessions/w 2 w 30 min/session Total = 300 min	Pad test 1 h	Significant reduction in pad weight for the EMS group ($p < 0.05$)	Score = 30 Good quality
Li *et al.*, 2020 China [41]	RCT	67	Women (31)	High frequency (50 Hz); intravaginal; device not specified	5 sessions 30 min/session Total = 300 min	PFMS (perineometer & oxford scale) PFIQ-7 IIQ-7	No significant difference of muscle strength (oxford scale) between the two groups; in the EMS group the mean value of EMG in endurance was significantly improved ($p < 0.001$)	Low risk of bias

Table 2. Continued.

Author/country	Study design	Sample size	Participants (median age, years)	EMS type; mode; Tool used	Intervention parameters	Outcome measures	Relevant findings	Risk of bias/quality assessment
Lim *et al.*, 2021 South Korea [42]	Prospective cohort	54	Women (51)	Low frequency (27 Hz); external application; Kegel Smart	2 sessions/d 8 w 15 min/session Total = 1800 min	PFMS (perineometer) BFLUTS KHQ	The EMS group achieved significantly greater reductions in LUTS ($p < 0.001$) and improvement in UI–related quality of life ($p = 0.01$), peak PFM contraction pressure ($p = 0.01$), mean pelvic muscle contraction pressure ($p < 0.001$), and duration of PFM contractions s ($p < 0.001$) when compared to the control group	Score = 35 Good quality
Liu *et al.*, 2018 China [43]	Prospective cohort	72	Women (56)	High frequency (80 Hz); intravaginal; PHENIX	2 sessions/w 8 w 30 min/session Total = 480 min	PFMS (perineometer) CIQ-UI SF	Both groups saw significant improvement in the frequency of UI episodes after 8-weeks ($p < 0.01$); participants who used EMS saw greater improvement than those who only did PFMT ($p < 0.01$)	Score = 31 Good quality
Lu *et al.*, 2020 China [44]	Prospective cohort	180	Women (30)	High frequency (80 Hz); intravaginal; PHENIX	2 sessions/w 12 w 15 min/session Total = 450 min	PFMS (perineometer)	Maximal urethral closure pressure, maximal urethral pressure, maximum urinary flow rate and electromyogram values in the EMS and control groups were significantly increased after treatment, and the values in the EMS group were greater than those in the control group (all $p < 0.05$)	Score = 26 Fair quality
Martín Prieto *et al.*, 2023 Spain [45]	Prospective cohort	27	Women (58)	Low frequency (35 Hz); intrarectal; MAPLe probe	1–2 sessions/w 10 sessions 30 min/session Total = 300 min	PFMS (perineometer)	Maximum voluntary manometric contraction, the average and peak resistance, the average general voluntary contraction, and average and peak voluntary contraction for both the external anal sphincter and the puborectalis significantly improved from baseline ($p < 0.05$)	Score = 28 Good quality

Table 2. Continued.

Author/country	Study design	Sample size	Participants (median age, years)	EMS type; mode; Tool used	Intervention parameters	Outcome measures	Relevant findings	Risk of bias/quality assessment
Mundet *et al*., 2021 Spain [46]	RCT	180	Women (61)	Low frequency (35 Hz); intervaginal; Elpha 3000 EMS unit +Periform+ vaginal probe *vs.* Low frequency (35 Hz); extravaginal; Elpha 3000 EMS unit with surface electrodes	5 sessions/w 12 w 30 min/session Total = 360	PFMS (perineometer) ICIQ	Improvement was across all 4 groups with the intervaginal EMS group demonstrating the most notable improvement across PFM characteristics. There was a statistically significant decrease in the ICIQ score at 3 months post-treatment in both EMS groups (intravaginal and extravaginal)	Some risk of bias concerns
Nicoletti *et al*., 2020 USA [47]	Prospective cohort	39	Women (63)	Low frequency (20 Hz); intervaginal; Urostym	2–3 sessions/w 8 w 15 min/session Total = 320 min	OAB-q HRQL	HRQL significantly improved post EMS ($p < 0.01$) Mean symptom bother scores reduced from 43.47 to 15.19 (t [38] = 9.05, p = 0.00), and HRQL scores improved from 66.35 to 94.50 (t [32] = –7.70, p = 0.00) following the intervention	Score = 30 Good quality
Oldham *et al*., 2021 UK [48]	RCT	86	Women (46)	High frequency (125 Hz); intravaginal; Pelviva	3–4 sessions/w 12 w 30 min/session Total = 180	Pad test (1 h) ICIQ-U PGI-I PISQ-IRI	Significant improvement scores on ICIQ-UI ($p < 0.01$), PGII ($p < 0.001$), PISQ-IR ($p < 0.01$) for EMS group when compared to control	Low risk of bias
Ptaszkowski *et al*., 2020 Poland [49]	RCT	41	Women (64)	High frequency (50 Hz); HIFEM external application; Solus Talen	1 single session 20 min/session Total = 20 min	PFMS (electromyograpy) ICIQ-SF	In the EMS group, there was a significant improvement in the surface electromyography measurements of PFM activity ($p < 0.05$); at the 1-hour follow up, PFM activity was higher by almost 2 µV ($p < 0.001$)	Some risk of bias concerns

Table 2. Continued.

Author/country	Study design	Sample size	Participants (median age, years)	EMS type; mode; Tool used	Intervention parameters	Outcome measures	Relevant findings	Risk of bias/quality assessment
Rodrigues *et al*., 2019 Brazil [50]	RCT	35	Women (58)	High frequency (50 Hz); intravaginal; device not specified	1 session/w 6 sessions 6 w 20 min/session Total = 120 min	PFMS (oxford scale) ICIQ-UI	PFMS in the vibratory group improved significantly in relation to the EMS group (p = 0.026); ICIQ-UI improved significantly for both groups ($p < 0.05$)	Low risk of bias
Samuels *et al*., 2019 USA [14]	Prospective cohort	75	Women (55)	High frequency (>10 kHz); HIFEM external application; Emsella	2 sessions/w 3 w 6 sessions 28 min/session Total = 168 min	Pad test (# of pads used) ICIQ-SF	An average improvement of 64.42% in ICIQ-SF score was observed after the 6-week follow-up ($p < 0.001$), the reduction of absorbent pad use averaged 43.80% after the sixth treatment and 53.68% at 3 months (both $p < 0.001$)	Score = 28 Good quality
Samuels *et al*., 2020 USA [27]	Prospective cohort	31	Women	High frequency (>10 kHz); HIFEM external application; Emsella	2 sessions/w 6 sessions Total = 168	ICIQ-UI FSFI PISQ	Initial ICIQ-UI scores were significantly improved at 1, 3 and 6 months respectively ($p < 0.001$), FSFI scores were significantly ($p < 0.001$) improved at 1, 3 and 6 months; PISQ scores also showed significant ($p < 0.001$) increases at 1, 3 and 6 months	Score = 11 Very poor quality
Scaldazza *et al*., 2017 Italy [51]	RCT	60	Women (59)	Low frequency (20 Hz); intravaginal; device not specified	3 sessions/w 10 sessions 6 w 60 min/session Total = 1800 min	OAB-q SF PGI-I	A reduction in daily voiding episodes was found both with EMS+PFMT and with percutaneous tibial nerve stimulation (PTNS) with a significant difference in the group of participants undergoing percutaneous tibial nerve stimulation ($p < 0.05$). The PGI-I showed improvements in both groups, favouring the PTNS group. This study demonstrates the effectiveness of PTNS and EMS with PFMT in women with OAB, but greater improvements for PTNS	Some risk of bias concerns

Table 2. Continued.

Author/country	Study design	Sample size	Participants (median age, years)	EMS type; mode; Tool used	Intervention parameters	Outcome measures	Relevant findings	Risk of bias/quality assessment
Silantyeva *et al*., 2021 Russia [28]	Prospective cohort	95	Women (31)	High frequency (>10 kHz); HIFEM external application; Emsella BTL *vs.* Low frequency (10 Hz); intravaginal; BioBravo portableEMS	2–3 sessions/w 4–5 w 10 sessions Total = 224 min	PFMS – (perineometrey) PFIQ-7	PFIQ-7 scores significantly improved for participants in the HIFEM group ($p <$ 0.001). This study documented that the HIFEM procedure was significantly more effective than low frequency EMS in treatment of PFDS in postpartum women. Both the objective and subjective evaluation indicates more profound effects of HIFEM	Score = 33 Good quality
Silantyeva *et al*., 2021 Russia [28] *	Prospective cohort	95	Women (31)	High frequency (>10 kHz); HIFEM external application; Emsella (BTL) *vs.* Low frequency (10 Hz); intravaginal; BioBravo portableEMS	2–3 sessions/w 4–5 w 10 sessions Total = 224 min *both interventions administered matched parameters	Transperineal-US PFDI-20	Significant improvement in PFDI-20 score ($p < 0.001$) in both HIFEM and low frequency EMS group compared to control group, with greater differences seen the HIFEM group ($p < 0.001$)	Score = 30 Good quality
Singhal *et al*., 2022 USA [29]	Prospective cohort	49	Women (59)	High frequency (>10 kHz); HIFEM external application; Emsella (BTL)	2 sessions/w 6 sessions 28 min/session Total = 168	BFLUTS-SF POP-Q score	Significant improvement BFLUTS-SF scores including Filling ($p < 0.05$), voiding ($p < 0.05$), and incontinence ($p < 0.001$). Significant improvement observed in stage 3 & 2 prolapse ($p < 0.001$)	Score = 27 Fair quality
Wang *et al*., 2022 China [52]	Retrospective study	78	Women (48)	Low frequency (33 Hz); intravaginal; PHENIX	Protocol 1 10 min EMS sessions *vs.* Protocol 2: 15 min EMS sessions *Number of sessions not reported	I-QOL PISQ-12 PFMS (OS)	The longer EMS protocol (15 min EMS group) had improved PFM parameters than the 10 min EMS group. There were no other between group differences	Score = 30 Good quality

Table 2. Continued.

Author/country	Study design	Sample size	Participants (median age, years)	EMS type; mode; Tool used	Intervention parameters	Outcome measures	Relevant findings	Risk of bias/quality assessment
Weber-Rajek *et al.*, 2020 Poland [53]	RCT	111	Women (68)	High frequency (50 Hz); HIFEM external application; NeoControl chair	3 sessions/w 4 w 15 min/session Total = 180 min	RUSI GSES BDI KHQ	A statistically significant decline in depressive symptoms (BDI-II) and an improvement in urinary in- continence severity (RUIS) and quality of life (KHQ) were found in both EMS and PFMT groups ($p < 0.05$)	Low risk of bias
Yang *et al.*, 2021 Taiwan [54]	Retrospective cohort	73	Women (59)	Low frequency (20 Hz); intervaginal; Urostym	2 sessions/w 12 w 15 min/session Total = 480	PFMS (perineometry) UDI-6 IIQ-7	Vaginal pressure in the total study population, SUI, and MUI groups increased significantly at week 6 (p = 0.000, 0.000, & 0.015, respectively) and week 12 (p = 0.000, 0.000, & 0.002, respectively). UDI-7 and IIQ-7 scores improved significantly. The intervention was particularly effective for subjects with SUI	Score = 29 Good quality
Yildiz *et al.*, 2021 Turkey [55]	RCT	62	Women (55)	Low frequency (10 Hz); intervaginal; Enraf Nonius Myomed	2 sessions/w 8 w 25 min/session Total = 400 min	PFMS (perineometey) OAB-V8 IIQ-7	The severity of incontinence, frequency of voiding, frequency of incontinence episodes, nocturia, number of pads used, symptom severity, and quality of life parameters were all significantly improved in the EMS group ($p < 0.05$)	Low risk of bias
Yildiz *et al.*, 2022 Turkey [56]	RCT	52	Women (57)	Low frequency (10 Hz); intervaginal; Enraf Nonius Myomed	5 sessions/w 8 w 20 min/session Total = 800 min *vs.* 2 sessions/w 8 w 20 min/session Total = 400 min	PFMS – (perineometey) OAB-V8 IIQ-7	All outcomes were significantly improved in both the EMS groups (treatments 2x and 5x per week; $p < 0.05$); there were no significant differences in parameters between the two groups at the end of the treatment	NA

Table 2. Continued.

Author/country	Study design	Sample size	Participants (median age, years)	EMS type; mode; Tool used	Intervention parameters	Outcome measures	Relevant findings	Risk of bias/quality assessment
Zhou *et al*., 2020 China [57]	RCT	720	Women (27)	High frequency (80 Hz); intervaginal; PHENIX	2 sessions/w	PFMS – (perineometry)	The EMS group showed significantly improved POP-Q scores compared with the control group ($p < 0.05$), ICI-Q-SF in was also significantly improved ($p < 0.05$). This study demonstrates that patients with postpartum	Low risk of bias
					8 w	ICI-Q-SF	PFDS respond favorably to intense EMS when combined with PFMT	
					15 min/session Total = 240	PFIQ-7		
Zhu *et al*., 2022 China [58]	Prospective cohort	110	Women (28)	High frequency (80 Hz); intervaginal; device not specified	2 sessions/w	ICIQ-SF	ICIQ-SF and I-QOL scores in the study group (EMS intervention) were significantly better ($p < 0.05$) than control	Score = 29
					5 w 20 min/session Total = 4050 min	I-QOL PFDI-20		Good quality

Summary of the relevant findings from the peer-reviewed literature.

EMS, electrical muscle stimulation; HIFEM, high intensity focused electromagnetic stimulation (frequency of 50 Hz, magnetic stimulation); RCT, randomized controlled trial; UI, urinary incontinence; POP, pelvic organ prolapse; PFMT, pelvic floor muscle training; PFMS, pelvic floor muscle strength; FI, fecal incontinence; SUI, stress urinary incontinence; OAB, overactive bladder; MUI, mixed urinary incontinence; UUI, urge urinary incontinence; w, week; UDI-6, urinary distress inventory-6.

Outcome Measures: PFDI-20, pelvic floor disability index; PGI-S, patient global impression of severity; PGI-I, patient global impression of improvement; I-QOL incontinence quality of life; ICIQ-UI, international consultation on incontinence questionnaire urinary incontinence short form; PISQ-IR, pelvic organ prolapse/urinary incontinence sexual questionnaire; IIQ-7, incontinence impact questionnaire; BFLUTS-SF, Bristol's female lower urinary tract symptoms questionnaire; FISI, fecal incontinence severity index; FISS, fecal incontinence severity score; FSFI, female sexual function index; CCFIS, cleveland clinic fecal incontinence score; FIQL, fecal incontinence QOL scale; PFIQ-7, pelvic floor impact questionnaire; PISQ-IRI, pelvic organ prolapse/urinary incontinence sexual questionnaire; ICIQ-LUTS, international consultation on incontinence questionnaire lower urinary tract symptoms; BDI-II, Beck depression inventory-II; KHQ, King's health questionnaire; RUIS, the revised urinary incontinence scale; OAB-Q, overactive bladder questionnaire; * indicates a published abstract.

For the twenty included studies that used intravaginal/ rectal stimulation, three used the PHENIX (20–80 Hz), Enraf Nonius (10 Hz), and UroStym (20 Hz) devices. The MyoPlus4 (20 Hz), Pelviva (2–125 Hz), MAPle Probe (35 Hz), Elpha 3000 (35 Hz), BrioBravo (10 Hz) and MyoMed (40 Hz) were also used. Several studies did not specify the devices used (Table 2).

3.5 EMS Intensity

A total of 19 studies used high-frequency stimulation (≥50 Hz), including 8 that used HIFEM (see Table 2). HIFEM therapy is an emerging external EMS modality that proposes to evoke a supramaximal contraction through a high frequency of action potentials in muscle tissue, with simultaneous magnetic stimulation [14]. Three included studies did not report the frequency of the stimulation.

4. Discussion

Although the existing literature base has been clear with respect to the benefit of using traditional low-intensity intervaginal EMS to improve outcomes among women with PFD, insight related to more novel forms of EMS, particularly those that are higher intensity and are applied externally is limited. Therefore, in this review we scoped, summarized and critically evaluated the available research investigating the impact of all current forms of EMS on PFDs in females. A large proportion of the reviewed studies pertained to the use of traditional low intensity (<50 Hz) intravaginal EMS protocols. Our analysis confirms what has been previously shown, and supports the use of these tools a conservative care tool for PFD. The most recent International Consultation on Incontinence (2023) indicates that these EMS tools have a grade B evidence recommendation to be used in combination with PFMT for women with UI [1].

The next most common form of EMS studied, used high frequency (>50 Hz), externally applied EMS, that also incorporated a magnetic stimulation component (HIFEM). In addition to demonstrating improvement of outcomes across all studies, we noted that protocols for HIFEM required less time when compared to all other forms of EMS (Table 2). Four different tools were analyzed in our review, however, the most studied HIFEM device was the Emsella Chair (BTL Technologies), used in 6 studies [2,14,15,27–29]. Only 1 of these studies was an RCT [15] while the rest were prospective cohort studies, one of which was high risk of bias (Table 2). The consistency of improvement on outcomes across studies is important to note as is the fact that two studies compared Emsella to traditional low frequency EMS and both demonstrated outcomes were more favourable in the Emsella HIFEM group [2,28].

In considering what might improve the efficacy of Emsella, over other forms of EMS, we note that Emsella uses a frequency of energy significantly higher than other HIFEM tools [59]. Further, when considering the potential benefit of all HIFEM tools, given the shorter intervention times, what needs to be considered is the pulsed electromagnetic component of energy that is incorporated into these therapies. Interestingly, all studies using HIFEM referred to the mechanism of action being related to strengthening of the pelvic floor. It is established the EMS is an effective rehabilitation strategy for muscle hypertrophy development and that positive muscle adaptions occur even with low intensity and low frequency applications [60]. However, a cited difference with respect HIFEM is that it induces electrical currents selectively in the PFM by mechanism of electromagnetic induction [61]. As magnetic field passes any medium without attenuation of the energy, the induced contractions may be achieved at greater depths and intensities [62] to possibly provide better outcomes. In addition, beneficial immune system mechanisms have been established with the use of pulsed electromagnetic frequency and such mechanisms should be further explored with respect HIFEM as a tool to assist with PFDs [63]. The mechanism of Pulsed Electromagnetic Fields (PEMFs), for example, is known to regulate cell proliferation, immune modulation, and inflammation responses through a variety of underlying molecular mechanisms with strong anti-inflammatory effects [64].

In the present review, only research examining EMS tools were examined; therefore, interventions examining magnetic stimulation in isolation were excluded. However, evidence from a systematic review and meta-analysis of 17 RCTs indicates that magnetic stimulation is effective in the treatment of urinary incontinence and improves quality of life in people living with SUI (i.e., extracorporeal magnetic stimulation) [65,66]. In the meta-analysis, significant improvements were noted on assessment measures of quality of life, number of daily pads used, and number of incontinence events [65]. Research suggests that the pulsed electromagnetic fields can penetrate pelvic floor muscles and strengthen them by stimulating pelvic floor nerves to contract [66,67]. The mechanism of action warrants further investigation, comparing extra- and intra-vaginal, low and high-intensity and magnetic and non-magnetic EMS modalities. A recent scoping review examining the mechanism of action of EMS suggests that an anti-inflammatory response is at least partially responsible for the positive outcomes observed after EMS [68] which may contradict previously held beliefs about the impact of EMS on pelvic floor muscle tone.

Four studies, all of which were RCTs and determined to be low risk of bias, studied a novel tool called EasyK7. Like the HIFEM tools, the EasyK7 administers energy externally *vs.* intravaginally. However, unlike HIFEM, this tool uses low frequency EMS (25 Hz) and does not have an additional magnetic stimulation component; despite this, all four studies demonstrated significant improvement across all outcomes with the use of EasyK7. It should be noted that the same participant group is used for all studies and thus further study of such a form of EMS is needed.

Due to the heterogeneity of the types of EMS used, protocols and outcomes measures used, which included a range of physical and self-report measures, it was not possible pool the data. It is not known, based on the information available from the included studies, why certain treatment protocols were used in the included studies. It is suspected that manufacturer recommendations were used in the included studies, rather than observing treatment effects throughout the duration of exposure to EMS. Moreover, it is not known how any benefit of EMS is maintained over time or how the benefit of EMS interacts with other aspects of clinical care beyond the scope of the trials included, which did often include EMS within the context of other PFM rehabilitation strategies.

The findings of the present review are also positive for individuals whose care preference does not include intravaginal or intrarectal care. The lack of acceptance of intervaginal care spans the landscape of PFDs and lumbopelvic pain [69]. Further, EMS may be particularly useful in women living with SUI or who are unable to perform voluntary muscle contractions: some research suggest this exceeds 50% of females [17,18]. Extra-vaginal EMS devices tend to be more costly when compared to intra-vaginal devices intended for a person's use at home and, as such, a variety of feasibility and acceptability factors beyond the scope of this review are likely important to consider when providing individualized care. It is also unclear if participants in the included research studies were paying for the EMS treatments they received. It must be considered that the duration of treatments may have been dependent on what was determined as a feasible cost, rather than an established protocol. However, high intensity, extra-vaginal EMS modalities, especially those like HIFEM with a magnetic component, do have higher costs and therefore may not present as a feasible treatment option for all people living with PFDs.

Future large-scale high-quality research interventions are required in order to determine the clinical utility of different EMS protocols, particularly novel HIFEM protocols. Ongoing research should be conducted to standardize protocols for better clinical implementation of EMS modalities for the treatment of PFDs in both females and males.

Limitations

Although this scoping review provides valuable insight related to the current landscape of EMS tools to support PFD, the current state of the science did not allow for the needed analysis to optimally guide clinical reasoning. The included studies did not address the magnitude of benefits to included participants, patients' preferences when it comes to the use of EMS, or tolerability of the modalities. In fact, a wide variety of assessment and outcome measures were used in the studies included in this review, making it difficult to determine the clinical significance of EMS on these outcomes. Given rise in popularity of HIFEM technologies, and the associated large claims made by manufactures, further clarity on the use of these tools and the validity of these claims is needed. Currently six trails investigating HIFM forms of EMS are registered on https://ClinicalTrials.gov. Thus, conducting a systematic review and associated meta-analysis specifically on HIFEM when more studies are pushed is an important next step to guide practice. We note several of the studies included have low quality of evidence and high risk of bias. Such limitations are all recorded within Table 2.

5. Conclusions

EMS demonstrates improvement across outcomes for PFDs among adult women. In particular, the results of this review suggest that EMS may be particularly useful in women living with SUI or who those are unable to perform voluntary muscle contractions when pelvic floor muscle training is attempted. Novel forms of EMS that used HIFEM appear to require less time to achieve therapeutic effects when compared to low-intensity modalities and furthermore might be preferable due to the external application of EMS. However, more RCTs and associated heterogeneity across studies is needed to generalizes the findings of the studies included in this review.

Availability of Data and Materials

The data that support the findings of this study are openly available and are identified in the reference list of this review paper. The authors confirm that the data supporting the findings of this study are available within the articles referenced in this work and/or their supplementary materials.

Author Contributions

NG and SD co-led this work and established the aim and methods. PA performed the initial literature search together with a medical librarian (McMaster University). PA, CD, HA and KK carried out abstract and full article screening as well as data extraction. NG carried out the analysis, quality assessments, and drafted the manuscript. HA conducted the risk of bias assessments. SD, PA, CD and KK all assisted with manuscript revisions with SD taking a lead role. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

Not applicable.

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Conflict of Interest

The authors declare no conflict of interest. The WOMB Milton, Knew Life Physiotherapy, and Oakville Pelvic Health were not involved in the preparation and publication of the manuscript.

Supplementary Material

Supplementary material associated with this article can be found, in the online version, at https://doi.org/10.31083/j.ceog5111257.

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