

# Magnetic stimulation for female patients with stress urinary incontinence, a meta-analysis of studies with short-term follow-up

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## Abstract

**Background:** To determine the efficacy of magnetic stimulation (MS) in female patients with stress urinary incontinence (SUI) by performing a meta-analysis on peer-reviewed randomized controlled trials (RCTs).

**Methods:** PubMed, Embase, and Cochrane library were retrieved for any peer-reviewed original articles in English. Databases were searched up to July 2018. Included studies investigated effects of MS on SUI. The data were analyzed by review manager 5.3 software (Cochrane Collaboration, Oxford, UK).

**Results:** A total of 4 studies involving 232 patients were identified and included in present meta-analysis. Compared with the sham stimulation, the MS group had statistically significantly fewer leaks/3 days (MD = -1.42; 95%CI: -2.42 to -0.59;  $P = .007$ ), less urine loss on pad test (g.)/24h (MD = -4.99; 95%CI: -8.46 to -1.53;  $P = .005$ ), higher QoL scores (MD = 0.42; 95%CI: 0.02–0.82;  $P = .009$ ), and lower ICIQ scores (MD = -4.60; 95%CI: -5.02 to -4.19;  $P < .001$ ). MS presented higher cure or improvement rate, with a statistically significant improvement in UDI and IIQ-SF scores compared to sham stimulation. No MS-related adverse effects were reported in study.

**Conclusion:** MS leads to an improvement in SUI without any reported safety concerns and an improvement in patient quality of life. The long-term outcome of this technique remains unclear and is the subject of ongoing research.

**Abbreviations:** ICIQ = International Consultation on Incontinence Questionnaire, ICS = International Continence Society, KHQ scores = King's Health Questionnaire scores, LUTS = lower urinary tract symptoms, MS = magnetic stimulation, MUS = midurethral slings, PFMT = pelvic floor muscle training, QoL = quality of life, RCT = randomized controlled trial, SUI = stress urinary incontinence.

**Keywords:** extracorporeal magnetic innervation, magnetic stimulation, meta-analysis, stress incontinence, urinary stress incontinence

## 1. Introduction

Stress urinary incontinence (SUI), a chronic and debilitating condition, is defined as involuntary loss of urine on physical exertion, sneezing or coughing.<sup>[1]</sup> As a greater proportion of women survive into later life, there are more older women with the SUI than in previous years. The burden of SUI is increasingly

high in hospitalizations, home nursing, economics, and cost of pads, diapers, and bedding.<sup>[2]</sup> SUI symptoms are negatively associated with not only sexual function but mental health.<sup>[3,4]</sup>

AUA/SUFU guidelines recommend pelvic floor muscle training (PFMT) as the first-line treatment for SUI.<sup>[5]</sup> PFMT, more commonly known as Kegel exercises, should be performed several times a day and need to be conducted consistently over time for benefit to be sustained (e.g. 2–6 s/time, 3–8 groups/day,  $\geq 8$  weeks). Low compliance often led to poor results. As for surgical correction of SUI, midurethral synthetic slings (MUS) was regarded as an optimal choice with objective cure rates ranging between 83.9% and 100%.<sup>[6]</sup> Nevertheless, complications including pain, mesh erosion and extrusion, and wound infections usually made quality of life (QoL) worse.<sup>[7]</sup> Thus, patients with SUI who did not want to undergo surgical treatment were more likely to favor other types of conservative therapies.

Electrical stimulation (ES) was one of popular conservative therapies and was reported to be an effective treatment. However, pain and discomfort caused by percutaneous electrical current limited the use of ES.<sup>[8–10]</sup>

A few studies reported that magnetic stimulation (MS) was a noninvasive and effective intervention for SUI without obvious side effects, which led to significant improvements in urodynamic variables and a reduction in the frequency of leakage on pad testing.<sup>[11–14]</sup> The mechanism of MS was considered as the same as that of ES, which might not only contract the pelvic floor muscles, but simultaneously inhibit the antagonistic reflex mechanism for emptying the bladder.<sup>[15,16]</sup> However, other

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LP and XZ contributed equally to this work and should be considered co-first authors.

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research has reported little efficacy of MS for SUI, and the efficacy is still controversial.<sup>[17–19]</sup> We, therefore, conducted a systematic review and meta-analysis of the RCTs to evaluate the use of MS.

**2. Materials and methods**

**2.1. Search strategy**

This study was performed according to the Preferred Reporting Items of Systematic Reviews and Meta-Analyses (PRISMA) guidelines.<sup>[20]</sup> The PubMed, Embase, and Cochrane library were searched for studies published up to July 2018. The electronic search was performed to capture all relevant studies by performing the following search strategy: (urinary incontinence OR stress urinary incontinence OR stress incontinence) AND (magnetic stimulation OR magnetic stimulation therapy OR magnetics OR extracorporeal magnetic innervation OR magnetic therapy OR conservative treatment) AND (clinical trials OR RCT). Furthermore, relevant conference proceedings and literature references of the EAU, IUGA, and ICS up to 2018 were searched manually. The procedure of retrieving and evaluating the papers was conducted independently by 2 authors (XZ and LP), and differences were solved through a discussion. This study does not need IRB approval because the data were obtained from studies freely available on the internet instead of being directly collected from institutions or patients.

**2.2. Study inclusion criteria**

Patients were diagnosed with SUI; Magnetic stimulation or sham therapy were used for SUI patients; Some outcome-reporting

parameters were recorded in study; Where there were duplications in congress abstracts or published journals, the data were rechecked to verify equivalence, and the most up-to-date or complete studies were eligible.

**2.3. Study exclusion criteria**

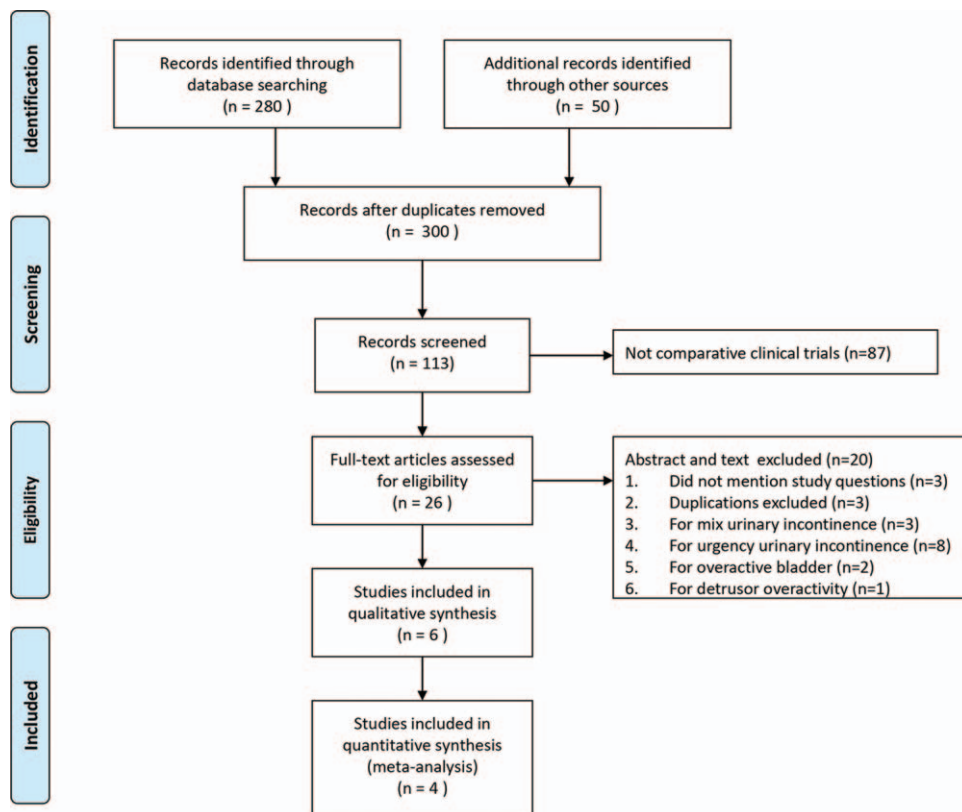
Studies were excluded according to the following criteria: the study type was a letter, review, comment, or case report; there was a lack of a comparative placebo-controlled group and quantitative data; patients were diagnosed with mixed SUI or urgency urinary incontinence and undergoing several different treatments. Selection process was shown in Figure 1.

**2.4. Study quality assessment**

The quality of the included RCTs was assessed according to the Cochrane Collaboration Reviewers’ Handbook<sup>[21]</sup> by LP and XZ. The quality standards consisted of generation of randomization sequences, allocation concealment, blinding, incomplete outcome data, freedom from selective reporting, and freedom from other biases. The results of assessment were shown in Table 1.

**2.5. Outcomes**

To evaluate the efficacy of MS, the primary outcomes of interest were considered as urine loss on pad test per day, number of leaks in a 3-day voiding diary, changes in urodynamic parameters, improvement rate, QoL scores, International Consultation on Incontinence Questionnaire (ICIQ) scores and KHQ scores



**Figure 1.** Flow diagram of evidence acquisition.

**Table 1**  
The details of included studies.

Author, year	Sample size(n) MS/Sham	Study design	Inclusion criteria	MS				Length of follow-up	Quality assessment	Outcome measures
				location	Intensity	Frequency	Duration			
Fujishiro et al <sup>[22]</sup> 2000	31/31	RCT	≥1 episodes of leaks recorded in a 3-day voiding diary, 2 gm. or more urine loss on a 1-hour pad test, no disorders possibly causing any LUTs	S3 roots	50%	15Hz, 5 s/min	30 min	1 week	High risk	1 No. of leaks 2 Pad test/g (24 hour) 3 QoL scores
Manganotti et al <sup>[23]</sup> 2007	10/10	RCT	≥1 episodes of urine loss recorded in a 3-day voiding diary, 2g or more urine loss in a 1-h pad test or a positive standardized stress test	S2-S4 roots	60% of the maximal	15Hz, 3 s/min	15 min	1 week	Low risk	1 Pad test/g (24 hour) 2 The KHQ scores 3 QoL scores 4 Stress test
Yamanishi et al <sup>[21]</sup> 2017	18/12	RCT	Women with urodynamic SUI refractory to PFMT for more than 12 weeks and who did not want to undergo surgery	Pelvic floor	Maximum	50 Hz, in 5-s on/5-s off cycles	20 min	10 weeks	Low risk	1 No. of leaks 2 Pad test/g (24 hour) 3 ICIQ-scores 4 QoL scores 5 ALPP
Lim et al <sup>[24]</sup> 2017	60/60	RCT	Female aged ≥21 years old, demonstrated urine leak on coughing, had ICIQ-UI SF score of ≥6 points	Pelvic floor	Maximum	50 Hz in an 8-s on, 4-s off, 2 sessions /week	20 min	14 months	Low risk	1 ICIQ-score 2 Pad test/g (24 hour) 3 No. of leaks

ALPP=abdominal leak point pressure, ICIQ=International Consultation on Incontinence Questionnaire, KHQ scores=King's Health Questionnaire scores, LUTs=lower urinary tract symptoms, MS=magnetic stimulation, PFMT=pelvic floor muscle training, QoL=quality of life, RCT=randomized controlled trial.

(incontinence impact). UTI, pain, discomfort, new depression, influence on social life and personal relationship were regarded as the secondary endpoints to evaluate safety.

## 2.6. Statistical methods

Review Manager 5.3 (Cochrane Collaboration, Oxford, UK) was used to perform all calculations and data manipulations. Heterogeneity was evaluated by  $I^2$  tests, with significance set at  $P < 0.05$ .  $I^2$  values of 25%, 50%, and 75% corresponded to low, medium, and high levels of heterogeneity, respectively. The fixed-effect method was used for studies without significant heterogeneity, and random-effect method was used with  $I^2$  values  $\geq 50\%$ .

## 3. Results

### 3.1. Characteristics of the included studies

A total of 330 studies were identified based on a defined search strategy. Around 87 papers were excluded for non-RCTs or nonclinical trials and 26 studies with different base line or different diagnosis or different group settings were also excluded. The reviewers (LP and XZ) independently assessed the complete articles and made their selection in accordance with the eligibility criteria. Finally, 4 studies<sup>[22–25]</sup> were eligible for systematic review after critical evaluation. The main characteristics of studies identified were presented in Table 1.

### 3.2. Synthesis of results

As shown in Figure 2, compared to the sham stimulation, MS group had a significantly less no. of leaks/3 days (MD = -1.42; 95%CI: -2.42 to -0.59;  $P = .007$ ) (Fig. 2 A), less urine loss on pad test (g)/24h (MD = -4.99; 95%CI: -8.46 to -1.53;  $P = .005$ ) (Fig. 2B), higher QoL scores (MD = 0.42; 95%CI: 0.02 to 0.82;  $P = .009$ ) (Fig. 2C), and lower ICIQ scores (MD = -

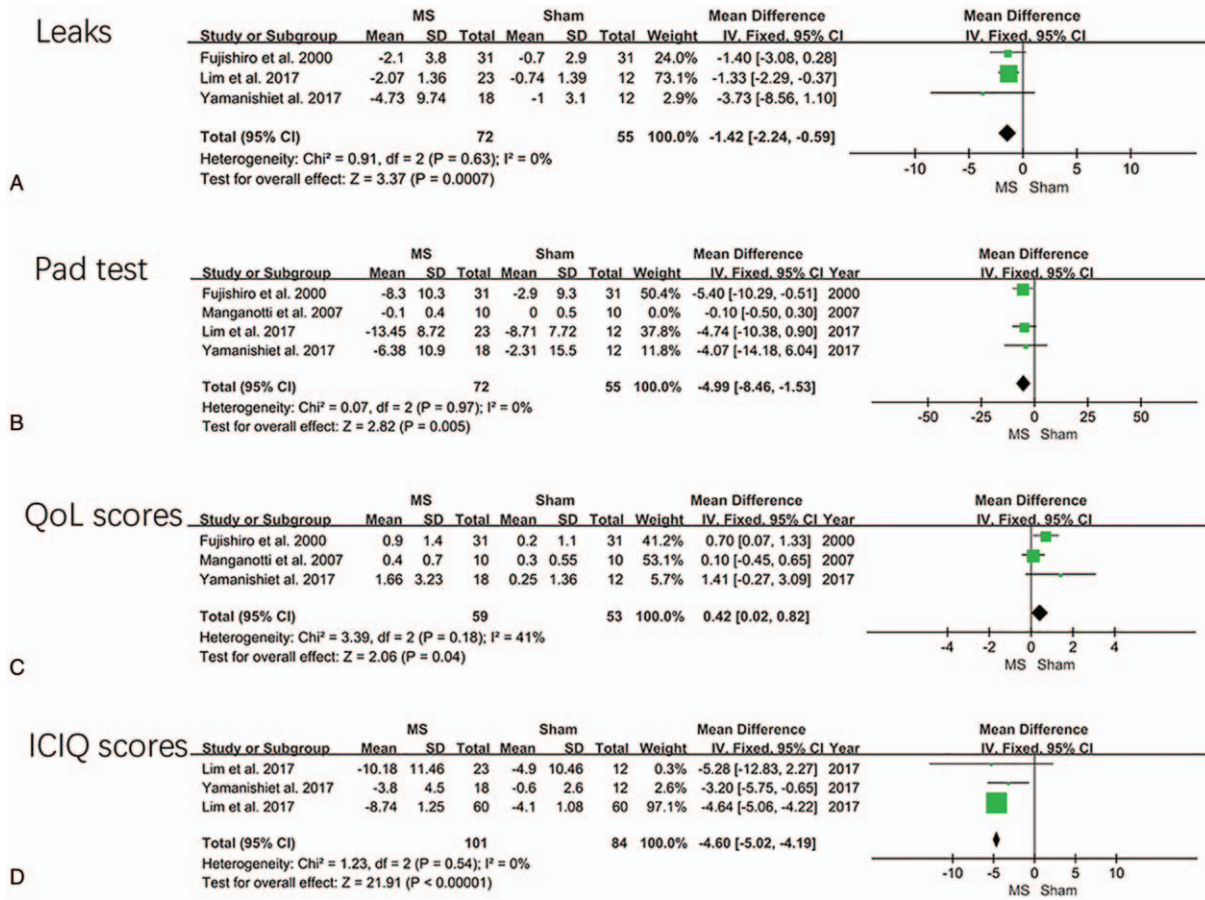
4.60; 95%CI: -5.02 to -4.19;  $P < .001$ ) (Fig. 2 D). No publication bias was identified (Fig. 3).

The improvement rates in Fujishiro et al in MS and sham group were 74% and 32%, respectively. In Lim et al, the improvement rate was 60% in the experimental group compared to 15% in the control group. Studies reported no MS-related adverse effects.

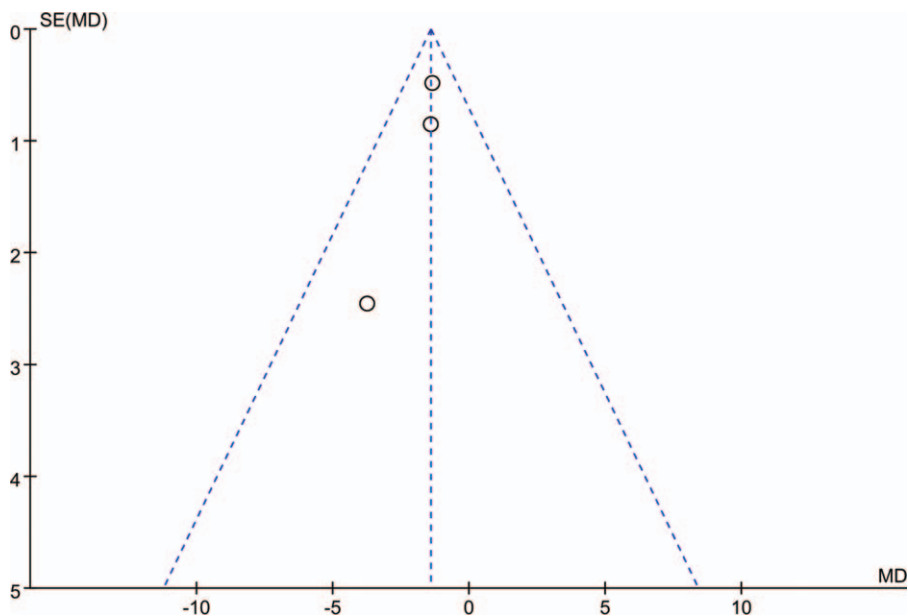
## 4. Discussion

To the best of our knowledge, this is the first study to investigate the efficacy of MS in female patients with SUI in short-term follow-up. MS significantly improved the symptoms of SUI, reduced the number of leaks and the average daily loss of urine, with lower ICIQ scores and improved QoL scores. Around 74% and 32%, 60% and 15% of improvement rates in MS and sham group were, respectively, reported in 2 RCTs.<sup>[23,25]</sup> Furthermore, a reduction in the number of leaks and urodynamic improvement, including an increase in maximum urethral closure pressure and change in abdominal leak point pressure, were recorded.<sup>[23,26]</sup> Gratifyingly, no MS-related side effects were reported. These results suggested that MS of the sacral roots or pelvic floor was useful, effective and safe for the treatment of SUI in the short-term follow-up.

MS is considered to improve PFM strength and endurance through repetitive contractions and exercises. The contraction of the detrusor muscle was inhibited by vigorous voluntary activation of the muscles of the pelvic floor.<sup>[15,27]</sup> Sherif et al<sup>[12]</sup> studied 7 patients following spinal cord injury with intractable detrusor hyper-reflexia and found a profound reduction in detrusor contraction and significant improvement of urodynamic parameters. In the study of Yokoyama et al,<sup>[28]</sup> cure rate of SUI after MS therapy was 52.9%, the one-hour urine loss reduced from 7.9 to 1.9g at 8 weeks. Significant improvement in both U-UDI scores and the Incontinence Impact Questionnaire Short Form total scores were recorded with a cure rate for SUI was 42.1% in study by Lo Tsia-Shu et al<sup>[14]</sup> Galloway



**Figure 2.** The change in number of leaks/3days (A), pad test /day (B), QoL scores (C), and ICIQ scores (D). df=degree free, ICIQ scores=International Consultation on Incontinence Questionnaire scores, MS=magnetic stimulation, QoL=quality of life, SD= standard deviation.



**Figure 3.** Publication bias of study.



et al<sup>[13]</sup> reported improvement and cure rates for MS therapy of 66% and 34%, respectively, within 6 months. These studies supported our conclusions and the mechanism of MS, which proved the effectiveness of MS and it a recommending treatment.

However, it should be kept in mind that, according to the included studies, our results were limited to 14 months, and the long-term efficacy was not clear. Ismail et al<sup>[19]</sup> proposed that there was no significant change in QoL scores and KHQ scores at 3-month follow up. As we know, if SUI could not be completely cured, even though the QoL scores were improved in the short time, long term these outcomes may not be preserved. A 3-year prospective study<sup>[29]</sup> of outcomes from MS for SUI showed continued benefit of MS for 1 year after therapy but gradually decreased and came close to baseline with high recurrence at the 3rd year. Another study by Hoscan et al<sup>[30]</sup> reported that the effects of MS did not last for 2 years. The long-term outcomes of this technique remain unclear.

Side effects related to the treatment were rare, which confirmed the safety of MS. Minimal or no adverse events reported in other studies from the USA,<sup>[13]</sup> Japan,<sup>[8,23]</sup> and Turkey,<sup>[31]</sup> supported that MS was tolerable and caused no anxiety in the majority of patients.

Although different regimes were used to treat SUI, the frequencies used varied between 15 and 50 Hz, and the length of treatment was not identical, clinical results were consistent excellent and unifying in the short-term follow-up. There was uncertainty about the optimum duration of treatment and the extent to which any symptomatic improvement was maintained after treatment was discontinued. The role of maintenance therapy was also unclear. When it comes to clinical decision making, further long-term research should focus on the best MS treatment model before MS is put into clinical practice. By performing an effective communication and a good counseling using useful communication skills, patients can obtain a clear understanding of clinical conditions and the risks and benefits of potential treatment options.<sup>[32]</sup>

A large number of patients had pelvic organ prolapse (POP) associated to SUI.<sup>[33]</sup> MS could be considered as a conservative and noninvasive treatment for concomitant SUI and de novo SUI. To determine the efficacy of MS for SUI in the presence of POP, a prospective study is needed.

According to the inclusion criteria defined previously, 6 articles<sup>[22–25,34,35]</sup> initially met the criteria. However, the research of But et al,<sup>[35]</sup> drawing the same conclusion with our study, was dedicated to urinary incontinence including stress, urgency, and mixed incontinence and did not specifically refer to stress incontinence. Tsai et al<sup>[34]</sup> assessed mainly 2 questionnaires including the Urge-Urinary Distress Inventory and the Overactive Bladder Questionnaire, making it difficult to analyze with other studies. Thus, these 2 articles were eventually excluded.

The limitations of the present study are listed as follows. First, its small sample size and insufficient statistical power. Second, the stimulation parameters and duration of the studies were not consistent, which makes us doubt whether meta-analysis can be carried out. However, the results based on RCTs were excellent despite inconsistent variables. Third, when analyzing on the data of Pad test, a huge heterogeneity that most likely caused by incomplete experimental design was recorded if we added the study by Manganotti et al<sup>[24]</sup> to the analysis. Thus, this study data was finally excluded by performing sensitivity analysis. Further well-designed RCTs for a long-term follow-up with a large sample size are needed.

## 5. Conclusion

In the short term, MS significantly improved the symptoms of SUI, reduced the number of leaks/3days and the daily loss of urine, with lower ICIQ scores and improved QoL scores. Although the beneficial effects of MS are temporary and not an alternative to surgical treatment, it can be considered as a conservative and noninvasive treatment approach in the management of SUI in patients either ineligible for or unwilling to undergo surgery.

## Author contributions

Each author contributed to the Manuscript has been changed as follows:

**Data Collection, Data analysis and Data curation:** Liao Peng, Xiao Zeng.

**Protocol/project development and Project administration:** Liao Peng, De-yi Luo

**Resources:** De-yi Luo.

**Supervision and Formal analysis:** Hong Shen, De-yi Luo.

**Validation and Conceptualization:** Hong Shen.

**Visualization:** Hong Shen, De-yi Luo.

**Writing – original draft and software:** Liao Peng, Xiao Zeng.

**Writing – review & editing:** Liao Peng, De-yi Luo.

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