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针灸临床实践指南
女性尿失禁

Clinical guideline on acupuncture and moxibustion—
Female urinary incontinence

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Foreword

This guideline aims to provide a set of standardized recommendations and protocols for treatment of female urinary incontinence with acupuncture and moxibustion.

This guideline is developed in accordance with the technical procedures and rules established by the Standardization Working Committee of the World Federation of Acupuncture-Moxibustion Societies.

This guideline is endorsed and published by the World Federation of Acupuncture-Moxibustion Societies.

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We also would like to appreciate Ms. Yang (China) as patient representative for her assistance and support for the development of this guideline.

Please note that some of the contents of this guideline may involve patents. The issuing organization of this guideline does not assume the responsibility for identifying patents.

Clinical guideline on acupuncture and moxibustion—Female urinary incontinence

1 Introduction

1.1 Terminology

1.1.1
conventional filiform needling therapy

The conventional filiform needle therapy in this guideline is a collective term of one type of filiform acupuncture therapy for female Urinary Incontinence (UI), which chooses main acupoints from the Conception Vessel (CV), the Spleen Vessel of Foot Taiyin (SP) and the Back-shu and Front-mu points of Urinary Bladder Vesssel (BL) at conventional needling depth, and applys filiform needle method as main intervention and electroacupuncture (EA) for enhancing needling sensation, according to syndrome differentiation of traditional acupuncture theory.

1.1.2
deep puncturing stimulation on lumbosacral acupoints therapy; **DPSLAT**

The Deep Puncturing Stimulation on Lumbosacral Acupoints Therapy (DPSLAT) in this guideline is a collective term of one type of acupuncture therapy for obtaining the main needling sensations of strong radiation sensation to the perineal region and sinking sensation of the vaginal region, which applys long filiform needles as acupuncture tools to puncture the acupoints on the lumbosacral region [such as Shangliao (BL31), Ciliao (BL32), Zhongliao (BL33), Xialiao (BL34)), Huiyang (BL35), Zhibian (BL54), etc.] at a depth of 50 mm or deeper, and EA for enhancing needling sensations.

1.1.3
moxibustion therapy

Moxibustion therapy in this guide means a collective term of one type of moxibustion including moxa stick moxibustion, moxa cone moxibustion and warm needling therapy as main intervention measures, which burns, warms, and irons at certain regions of the body surface or at certain acupoints for treating diseases, moxa being the main moxibustion material.Moxibustion therapy here is divided into: suspended moxibustion, warm needling moxibustion, indirect moxibustion, heat sensitive moxibustion.

Suspended moxibustion therapy: Main operation: Burn one end of the moxa stick, target at the acupoint or affected area where should be moxibusted, 2-3 cm away from the skin until it turned to be flushing in each treatment. The therapy here is divided into mild moxibustion, sparrow-pecking moxibustion and circular moxibustion.

Warm needling moxibustion therapy: Main operation: Filiform needle is punctured into acupoint, and appropriate reinforcement and reduction techniques are given after Deqi. In the retaining needle process, the pure and soft moxa is pinched at the end of the needle, or a moxa stick (cutting off a length about 2 cm) is inserted on the needle handle. Burn it. Remove the ash after burning the moxa, and pull out the needle.

Material interposed moxibustion: Main operation: Some material is interposed between moxa cone and the skin. The materials may use ginger or mashed herbs of Traditional Chinese Medicine (TCM) to treat female UI.

Heat sensitive moxibustion: Main operation: Before moxibustion, look for heat sensitive points first, then select special moxibustion stick to warm the heat sensitive points until the heat sensitive phenomenon disappears. Heat penetration and transmission of the heat sensitive points may stimulate the transmission of channel qi and make the qi reach the affected location.

1.1.4
pelvic floor muscle training; PFMT

Pelvic Floor Muscle Training (PFMT) could be used as an effective first-line treatment for Stress Urinary Incontinence (SUI), Urgency Urinary Incontinence (UUI) and Mixed Urinary Incontinence (MUI). At present, rehabilitation training for pelvic floor muscles includes Kegel exercise, pelvic floor muscle electrical stimulation therapy, biofeedback therapy, etc. Among them, Kegel exercise is the most commonly used in clinical practice. The main operations is as follows: continuous Pelvic floor muscle contraction (anal constriction movement) for no less than 3 seconds, relaxation for 2-6 seconds, repeating the above movement for 15-30 minutes, or doing 150-200 times anal constriction exercises every day. Evaluation was perfoemed after 3 months training in the outpatient clinic.

1.1.5
Medication for urinary incontinence

Current evidence-based medical therapy is primarily used as an alternative treatment for UUI. Medications commonly used in the treatment of UUI include anticholinergic agents (e.g., solifenacin) and β3 adrenoergic receptor agonists (e.g., mirabellone).

1.2 Aims and objectives

This guideline provides recommendations of acupuncture-moxibustion therapy for female Urinary Incontinence (UI) to meet international demand of clinicians and patients based on current clinical evidence. The international applicability, and patients values and wishes are also taken into account. This guideline intends to improve the effectiveness, safety and standardization of acupuncture-moxibustion treatment for female UI and promote international application of acupuncture-moxibustion for female UI in clinical practice.

1.3 Scope

This guideline applys to female UI.All types and different degrees of female UI may use this acupuncture and moxibustion therapy.The target population is female adult patients with UI.

1.4 Target audience

The target population of this guideline are worldwide professionals in clinical, teaching and scientific research related to female UI, including: ① acupuncturists; ② Traditional Chinese Medicine (TCM) practitioners; ③ urology practitioners; ④ teachers and students of medical schools or education and training institutions of TCM; ⑤ relevant personnel of Chinese medical research institutions.

1.5 Settings

The guideline is applicable to hospitals and clinics including department or office of acupuncture and moxibustion, and medical shools including major specializing in acupuncture-moxibustion, and research and evaluation institutions related to acupuncture.

1.6 Summary of recommendations

No.	Recommendations	Strength rating	Certainty of evidence
1	For female UI, conventional filiform needling therapy may be recommended, rather than no treatment or placebo acupuncture.	Conditional recommendation	Low
2	For female UI, conventional filiform needling therapy may be recommended, rather than PFMT or oral conventional medication.	Conditional recommendation	Very low
3	For moderate-severe female UI, PFMT or oral conventional medication combined with conventional filiform needling therapy may be recommended.	Conditional recommendation	Low
4	For female UI, DPSLAT may be recommended rather than no treatment or placebo acupuncture.	Conditional recommendation	Medium
5	For female UI, DPSLAT may be recommended, rather than PFMT or oral conventional medication.	Conditional recommendation	Low

(*continued*)

No.	Recommendations	Strength rating	Certainty of evidence
6	For moderate-severe female UI, PFMT or oral conventional medication combined with DPSLAT may be recommended.	Conditional recommendation	Very low
7	For female UI, moxibustion therapy may be recommended, rather than no treatment.	Conditional recommendation	Very low
8	For female UI patients, moxibustion therapy, PFMT or oral conventional medication may be recommended.	Conditional recommendation towards intervention or comparison	Very low
9	For moderate-severe female UI, PFMT or oral conventional medication combined with moxibustion therapy may be recommended.	Conditional recommendation	Very low
10	For female UI patients, the combination of filiform needling and moxibustion therapy may be recommended.	Conditional recommendation	Very low

1.7 Contacts

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2 Overview of the disease

2.1 Definition

International Continence Society (ICS) defines UI as involuntary loss of urine. European Association of Urology (EAU) classifies UI into Stress Urinary Incontinence (SUI), Mixed Urinary Incontinence (MUI), and Urge Urinary Incontinence (UUI)[1]. SUI refers to involuntary leakage of urine due to increased intraabdominal pressure (coughing, laughing, sneezing and exercising). In UUI, there is involuntary leakage of urine after an intense and sudden urge to urinate. MUI refers to concomitant SUI and UUI, accompanied by dysfunction of bladder sphincter.

2.2 Epidemiology

An epidemiological survey in Australia[2] found that 36.2% of Australian women suffered from UI, in which MUI was the most common with a prevalence of 14.6%, followed by UUI (11.3%) and SUI (10.4%). In China, female UI population was 18.9%, with an increasing trend with age, in which 50 to 59 years old were the peak ages for getting SUI (28.2%)[3]. In the United States, the prevalence of UI in women is about 17.1%, and the annual medical cost for UI is USD 30 billion[4].

Although UI is not a life-threatening disease, it has a great impact on patients' daily activities, mental well-being and social interaction. It may make patients depressed, helpless and anxious, esp. in the female. It affects the quality of life in female patients severely and is known as a "nonlethally social cancer".

2.3 Symptoms, signs and urodynamic examination

2.3.1 Symptoms

2.3.1.1 Stress urinary incontinence: according to the severity of subjective symptoms, SUI can be classified as follows: ① Mild: leakage of urine only occurs during coughing or sneezing, and does not need to use a urine pad; ② Moderate: leakage of urine occurs during daily activities such as running, jumping, fast walking etc., and needs to use a urine pad; ③ Severe: leakage of urine occurs even with slight movement and change of body position, and needs to use a urine pad.

2.3.1.2 Urge urinary incontinence: The main symptoms manifest as urgent, and/or frequent urination, nocturia, and inability to voluntarily control urination. Involuntary leakage of urine occurs immediately after the sensation of urination, which is often induced by activities and environment, such as the sound of running water, cold stimulation, etc.

2.3.1.3 Mixed urinary incontinence: it comprises symptoms of both SUI and UUI.

2.3.2 Signs

Physical examination should focus on finding and judging the causes of UI, which helps in formulating subsequent treatment plans. Physical examination of patients with UI mainly includes general examination, perineum/genitalia examination, neurological examination and other special tests.

2.3.2.1 General examination

Height, body weight and BMI index are related to the incidence of UI. In addition, surgical scars on the abdomen, abdominal and inguinal hernias, abnormal sag or eminence of the sacrococcygeal skin, palpably distended bladder and bladder filling degree in the lower abdomen, and spinal deformities should be examined.

2.3.2.2 Perineum/Genitalia examination

If SUI is suspected, the patient is placed in the bladder lithotomy position and the bladder is moderately full. When the patient is asked to cough or increase abdominal pressure, it is observed whether there is involuntary urine discharge from the urethra for confirming the existence of SUI. In female patients, the mobility of the bladder neck should be evaluated, esp. whether there is pelvic floor organ prolapse when coughing or increasing abdominal pressure. The function of pelvic floor muscle and the ability of patients to contract pelvic floor muscle should be evaluated.

2.3.2.3 Neurological examination

The purpose of a neurological examination in patients with UI is to eliminate UI caused by neurological diseases. Detailed neurological examination includes mental state, sensory function and reflex integrity. For patients with UI, the nervous system examination focuses on the sacrococcygeal examination, including the sensorimotor of both lower limbs and the perineum, etc. Clinically, the function of the external urethral sphincter is generally evaluated by the function of the anal sphincter. The most commonly used reflex is a light touch to the skin junction of the anal mucosa, which can cause contraction of the external anal sphincter muscle, called the anal reflex. If this reflex disappears, it often indicates sacral nerve injury. The examination of anal autonomic contraction can help to determine the innervation of pelvic floor muscles. The bulbocavernous reflex can reflect the local reflex condition of sacral marrow. The absence of this reflex indicates sacral nerve injury.

2.3.2.4 Special tests

Pad test: Pad test is possible to detect incontinence occurring over a certain period of time and quantify the amount of urine leakage by measuring changes in pad weight under standardized conditions. Pad tests can be performed from less than 1 h to 72 h, and short-time urine pad tests (1 h to 2 h) are usually performed in the doctor's office under a specific condition (activity or exercise). Short-term pad test results of no more than 1 h are mostly reliable if the patient's bladder volume is constant. The 1 h urine pad test is to let the patient drink 500 mL of water 15 min before the test, and then complete a series of exercises. The 1 h pad test defines the urine pad weight increase of more than 1 g as positive. The longer duration of the 24 h pad test can be carried out at home to make the measurement of incontinence closer to real life. Since no exercise mode is set, the 24 h pad test can quantify both SUI and UUI.

Bladder Stress Test: The stress test is positive if urine flows out of the external urethral orifice when the patient coughs, and vice versa, it is negative. Patients with SUI show positive results of the stress test, while patients with UUI show negative results. However, for some patients with UUI, coughing and other stimuli can cause the contraction of the detrusor muscle, resulting in a delay in the outflow of urine from the urethral opening, which is still defined as a negative result.

Cotton Swab Test: The disinfected and lubricated cotton swab was inserted into the urethra so that the tip of the swab was at the urethrovesical junction. The Angle between the swab and the horizontal line was measured during the patient's resting and Valsalva maneuver. Under normal circumstances, the angle should be $<15^\circ$, indicating normal anatomical support; if the angle is between 15° and 30°, it indicates that the result is uncertain; if the angle is $>30^\circ$, it indicates weak anatomical support and greater urethral mobility. Patients with simple SUI show Cotton Swab Test $>30^\circ$, while patients with MUI and UUI show the test $<30^\circ$.

2.3.3 Urodynamic examination

Urodynamic examination determines the types of UI based on hydrodynamics. At present it is the most effective method for the diagnosis of UI. This examination must be carried out without urinary tract infection, and pay attention to adhere to aseptic procedures and to prevent retrograde infection. Through urodynamic studies, classifying and typing of UI are carried out, so as to adopt targeted treatment methods.

For simple SUI with typical symptoms, routine urodynamic studies are not recommended to avoid excessive examination. Only B ultrasound or catheter is needed to measure residual urine volume $<$ 150 mL. However, for complex SUI, urodynamic studies are necessary. Urodynamic examination should be performed for complex SUI, which shows that the detrusor muscle is stable in the urine storage period, the detrusor muscle contractions are strong in the urination period, the urine flows out when coughing, and the residual urine can be $\geqslant$150 mL.

SUI is classified by urodynamic examination (especially for those whose clinical manifestations are not line with physical examinations). According to the abdominal leakage point pressure (ALPP), SUI is classified into: ① type Ⅰ: ALPP $\geqslant$90 cm H_2O, ② type Ⅱ ALPP 60 cm H_2O-90 cm H_2O, ③ type Ⅲ: ALPP $\leqslant$60 cm H_2O. Type Ⅰ and type Ⅱ indicate SUI with urethral hypermobility, and type Ⅲ refers to SUI with intrinsic sphincteric deficiency.

According to the maximum urethral closure pressure (MUCP), SUI is classified into: ① MUCP $>$ 20 cmH_2O (or $>$30 cmH_2O), which indicates SUI with urethral hypermobility; ② MUCP $\leqslant$20 cmH_2O (or $\leqslant$30 cmH_2O), which indicates SUI with intrinsic sphincteric deficiency.

The results of urodynamic examination of patients with UUI show small bladder volume, poor compliance, unstable detrusor contraction, no residual bladder urine. The treatment for UUI is completely different from SUI, so it is necessary to accurately distinguish between the two.

The diagnosis of MUI should be combined with the patient's clinical symptoms and the results of urodynamic examination, and should not be misdiagnosed or missed just because of the unclear results of urodynamic examination. The urodynamic findings of patients with MUI were not characteristic, and it was not a simple manifestation of SUI combined with UUI.

2.4 Modern medical treatment

At present,the main methods of modern medical treatment for female UI include conservative treatment and surgical treatment.After patients were evaluated for incontinence,treatment plans should begin with conservative treatment,including PFMT,drug therapy,and changes in behavior and lifestyle.Patients with poor response to conservative treatment or severe UI, anti-UI surgery can be taken,such as urethral injection of fillers,and retropubic sacral vaginal suspension,etc.

PFMT and medication therapy for urinary incontinence refer to 1.1.4 and 1.1.5.

3 Guideline development process

The development of this guideline refers to the GRADE methodology[9] and the WHO Handbook for Guideline Development[10].The development process mainly includes three key links:forming clinical problems and outcomes, constructing evidence body, and formulating recommendations and therapeutic protocols.

3.1 Development of clinical questions

Firstly,PICO structured clinical concern Survey questionnaire[11] was used to conduct an international survey on the target population,and 114 questionnaires from doctors were collected.The survey results suggest that the most concerned types of female UI are SUI,MUI and UUI.The most concerned interventions are filiform needle therapy,electroacupuncture and moxibustion therapy.The most concerned outcomes were frequency of UI,quality of life score of female UI patients,ICIQ-SF score.A preliminary list of clinical problems and outcomes was developed based on the clinical concerns of the target population.Through two rounds of modified Delphi GDG consensus,this guideline incorporates 10 clinical questions covering the most concerned elements of PICO.Through three rounds of modified Delphi GDG consensus,11 outcomes were included in this guideline,in order of importance: frequency of UI in 24 h,quality of life score,U-IIQ/U-UDI,ICIQ-SF,patient satisfaction score,amount of urine pads,adverse event rate,clinical economic indicators,urine leakage in 24 h/72 h,1 h pad test leakage,ancillary tests for the evaluation of urinary tract problems.

The modified Delphi consensus[12] rules for clinical questions and outcomes are as follows:

For clinical questions, importance was rated on a five-point Likert scale (“very important” = 5 points,“important” = 4 points,“generally important” = 3 points,“not too important” = 2 points,and “not important” = 1 point).For the outcome measures,the GRADE importance rating rule was used. Accordingly,the mean ($\overline{X}$) and coefficient of variation ($CV = SD/\overline{X}$) of this topic were calculated.

After completing the first round of the Delphi study, a consensus meeting was held on the clinical questions and outcomes of this guideline.After the GDG members have fully expressed their views,a second round of Delphi voting will take place.For clinical questions and outcomes,eligibility for inclusion in this guideline was: a mean importance score >3 and a CV≤25%. When the mean importance was <3 and CV was ≤25%, the corresponding clinical problems or outcomes were excluded. When CV >25%, the second round of conference discussion will be conducted around this item, and the third round of Delphi research will be conducted after full discussion. If the coefficient of variation for the relevant item remained higher than 25% in the third round of the Delphi study, the clinical problem or outcome was excluded.

3.2 Construction of evidence body

A systematic search was carried out based on the treatment of female UI with conventional filiform needle therapy, filiform DPSLAT, and moxibustion therapy respectively, in four major English databases (PubMed, Embase, Cochrane, Web of Science) and four major Chinese databases (CNKI, Wanfang, VIP, China Biomedical Literature Database) before May 15, 2022 to the establishment of the databases. Keywords "female urinary incontinence" "acupuncture" "moxibustion" were constructed. And search the international clinical trial register platform (https://trialsearch.who.int/Default.aspx), the American clinical trial register platform (https://www.clinicaltrials.gov/) and Chinese clinical trial registry (http://www.chictr.org.cn).

The inclusion and exclusion criteria were formulated according to the PICO element characteristics of the 10 clinical questions, and the literature features were extracted and the risk of bias was analyzed. Meta-analyses were conducted around different outcomes of each clinical question, and GRADE evidence quality (risk of bias, inconsistency, imprecision, indirection, and publication bias) was assessed on the body of evidence. The guideline development tool GDTpro[13] was used to generate the Evidence Summary Table (SoF) and the Evidence Decision Table (EtD).

Based on the multi-dimensional considerations of cost-effectiveness, health equity, acceptability and feasibility in the EtD framework, a questionnaire was designed to investigate the current status of acupuncture-moxibustion therapy for the intended user and the target population of the guideline. A total of 299 valid questionnaires (including 232 questionnaires from Chinese medical practitioners, 67 questionnaires from overseas medical practitioners). The feedback of medical practitioners was collected, and the evidence of health economics, acceptability and practicability of acupuncture-moxibustion was extracted and summarized. Supplement the relevant evidence in the EtD framework.

3.3 Development of recommendations

The recommendation opinions were produced by GDG members through the modified Delphi consensus after they fully grasped the evidence-based basis. First of all, after adequately reading the evidence body of each clinical problem (including in the literature feature table, risk of bias assessment table, SoF table and EtD framework) and consensus rules, GDG members made judgments about the twelve dimensions of the EtD framework, and gave the direction and intensity of recommendations for each clinical problem. The Working group made statistics on the results of the first round modified Delphi surveys of the EtD framework and recommendations. Then a GDG consensus meeting was held to introduce the body of evidence, consensus rules and statistical results of the first round of modified Delphi voting,and discuss in GDG members around the EtD framework for each issue.After extensive discussion,GDG members again voted on the EtD framework and recommendations. Acocrding to the results of the second round of modified Delphi survey and GRADE grid consensus rules,the working group formed recommendations

GRADE grid consensus rule [14] is as follows:

① The recommendation or disapproval of an intervention (as compared to a specific control) required approval by at least 50% of participants, with less than 20% choosing the control. Failure to meet this criterion results in a "conditionally recommended intervention or control".

② A recommendation must be strongly recommended by at least 70% of the participants if it is listed as strong rather than conditional.

The recommended therapeutic protocols were generated by the modified Delphi consensus after GDG members evaluate the effective protocol in the evidence body. The working group pooled RCT studies with positive results for key outcomes (e.g., frequency of UI, ICIQ-SF) in the body of evidence for convention filiform needling therapy, DPSLAT and moxibustion therapy, respectively. The population characteristics and intervention details of each included study were extracted to form specific acupuncture programs, and then summarized into multiple filiform needle and moxibustion treatment programs. The first round of modified Delphi survey was conducted among the acupuncture experts of GDG, and the importance score and coefficient of variation of different treatment plans were counted. An expert consensus meeting on acupuncture-moxibustion in GDG was held, at which each recommended protocol was fully discussed, and the second round of modified Delphi survey was conducted. Based on the findings, the working group determined recommendations for inclusion.

The modified Delphi consensus rules for therapeutic protocols are as follows:

For therapeutic protocols, importance was rated on a five-point Likert scale ("very recommended" = 5 points, "recommended" = 4 points, "generally recommended" = 3 points, "not recommended" = 2 points, and "very not recommended" = 1 point). Accordingly, the mean ($\overline{X}$) and coefficient of variation ($CV = SD/\overline{X}$) of this topic were calculated.

After completing the first round of the Delphi study, a consensus meeting was held for therapeutic protocols of this guideline. After the GDG members have fully expressed their views, a second round of Delphi voting took place. For therapeutic protocols, eligibility for inclusion in this guideline was a mean importance score >3 and a CV$\leqslant$30%. When the mean importance was <3 and CV was$\leqslant$30%, the corresponding therapeutic protocol were excluded. When CV $>$30%, hold a meeting discussion around this item, and conduct the second round of Delphi survey after full discussion. If the coefficient of variation for the relevant item remained higher than 30% in the third round of the Delphi study, the therapeutic protocol was excluded.

4 Recommendations

Question 1: Compared with no treatment or placebo acupuncture, can female UI patients benefit from conventional filiform needling therapy?
(1) Recommendation
For female UI, conventional filiform needling therapy may be recommended, rather than no treatment or placebo acupuncture. (Conditional recommendation, low certainty of evidence)
(2) Summary of findings
2 RCTs addressed this clinical question, including 4 outcomes. Among them, frequency of urinary incontinence in 24 h (critical outcome) is very low-quality evidence. The incidence of adverse events (important outcome), urodynamic examination-maximum bladder manometric volume (important outcome), urodynamic examination-initial sensation of bladder voiding (important outcome) are low-quality evidence. Compared with no treatment or placebo acupuncture, conventional filiform needling therapy showed moderate beneficial effects and trivial adverse effects in female UI treatment. Compared with no treatment or placebo acupuncture, conventional filiform needle therapy may be cost-effective and may increase health equity. In addition, the conventional filiform needling therapy is acceptable for patients and doctors, and has good feasibility. Based on these justifications, the GDG agreed that conventional filiform needling therapy is recommended for the treatment of female UI compared with no treatment or placebo acupuncture.
(3) Explanation
• Subgroup The patient population for which this recommendation is developed involved adult female UUI and MUI. This recommendation is applicable to all types of adult female UUI and MUI patients, and adult female SUI can also be referred to this recommendation. Conventional filiform needling therapy may be recommended the following female UI patient groups: ① female UI patients whose quality of life is affected by symptoms of urinary incontinence; ② female UI patients who are not resistant to filiform needling therapy.

(*continued*)

• Implementation Before the implementation of this recommendation, patients are recommended to see a doctor in the department of Urology for the diagnosis and state of UI. When implementing this recommendation, the consideration of this guide should be fully referred to. • Monitoring and evaluation Monitor whether more female UI patients receive conventional filiform needling therapy after the guidelines are issued. Evaluate the changes in efficacy indicators (frequency of urinary incontinence, quality of life score, urinary incontinence score, etc.), safety indicators (incidence of adverse events, etc.), health economic indicators (incremental cost-benefit ratio, incremental cost effect, incremental cost utility, etc.) and satisfaction with treatment in female UI patients after the implementation of this recommendation. • Research priorities To carry out high-quality RCT between conventional filiform needling therapy and no treatment/placebo acupuncture for female UI (especially SUI). Evaluate the efficacy and safety of conventional filiform needling therapy for special female UI populations (especially SUI). Evaluate the efficacy and safety of conventional filiform needling therapy for special female UI populations (old female UI, minor female UI, etc.). Evaluate the economic burden of disease and the health economics of conventional filiform needling therapy in treating female UI. Optimize the therapeutic protocol of conventional filiform needling therapy in treating female UI and compare the efficacy, safety, cost-effectiveness and patient preference of different therapeutic protocols.
(4) Application of recommendation
Conventional filiform needling therapy applies to all types and degrees of adult female UI patients. Conventional filiform needling therapy may be recommended when: ① female UI patients whose quality of life is impacted by symptoms of urinary incontinence; ② female UI patients who are not resistant to filiform needling therapy.

(*continued*)

(5) Recommended treatment protocol
• Selection of acupoints Abdomen:Zhongji(CV4),Guanyuan(CV3),Qihai(CV6),Dahe(KL12). Lumbosacral:Shenshu(BL23),Pangguangshu(BL28),Mingmen(GV4). Lower limbs:Sanyinjiao(SP6),Taixi(KI3),Weizhong(BL40),Fuliu(KI7). According to the condition,the above acupoints should be selected as appropriate.It is suggested that the abdominal acupoints should be combined with the lower limbs acupoints,the lumbosacral acupoints should be combined with the lower limbs acupoints,or the abdominal and lumbosacral acupoints should be combined with the lower limbs acupoints for treatment. • Operation Puncture with filiform needle at Zhongji(CV4),Guanyuan(CV3),Qihai(CV6) and Dahe(KL12) obliquely 30 to 40 mm in depth in the direction of pubic symphysis;Puncture Shenshu(BL23),Pangguangshu(BL28),Mingmen(GV4),perpendicularly 20 to 30 mm in depth;Routine needling depth at other points.When needling Zhongji(CV4),Guanyuan(CV3),Qihai(CV6) and Dahe(KL12),it is better to spread the needling sensation to the perineum and urethra.The sour,numbness,distending,heavy and so on needling sensation should be elicited in the other points. Reinforcing and reducing manipulation:Implement the reinforcing and reducing manipulation based on the principle of "Treating excess with reduction and treating deficiency with reinforcement". Duration of needle retention:20 to 30 minutes.The duration of treatment can be determined as appropriate based on factors such as the patient's condition and acceptability. • Treatment frequency At least 1 time/week,2 to 3 times/week is recommended,depending on the patient's condition,acceptability and other factors as appropriate. • Treatment course At least 4 weeks constitute a course of treatment,2 to 3 courses are recommended,depending on the patient's condition,acceptability and other factors as appropriate.

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• Other issues Use combinating points as appropriate according to the TCM pattern identification. Use the acupoints on the lumbosacral parts of Ciliao(BL32), Zhongliao(BL33), Huiyang(BL35), Baohuang(BL53) and Zhibian(BL54), etc. can be used with filiform needle according to the patient's condition and acceptability.

Question 2: Compared with PFMT or medication treatment, can female UI patients benefit equally or more from conventional filiform needling therapy?
(1) **Recommendation**
For female UI, conventional filiform needling therapy may be recommended, rather than PFMT or oral conventional medication. (Conditional recommendation, very low certainty of evidence)
(2) **Summary of findings**
5 RCTs addressed this clinical question. 3 RCTs of conventional filiform needling therapy and PFMT control including 7 outcomes. Among them, the incidence of adverse events (important outcome), urodynamic examination-detrusor pressure (important outcome) are low-quality evidence. ICIQ-SF score (critical outcome), urine leakage in 24 h (important outcome), urodynamic examination-maximum urine flow rate(important outcome), urodynamic examination-mean urine flow rate(important outcome), urodynamic examination-maximum urethral closure pressure(important outcome) are very low-quality evidence. 1 RCT of filiform needling therapy and oral tolterodine hydrochloride control including 2 outcomes. Among them, the incidence of adverse events (important outcome) is low-quality evidence. Frequency of urinary incontinence in 24 h (critical outcome) is very low-quality evidence. 1 RCT of conventional filiform needling therapy and PFMT combine with oral tolterodine tartrate control including 3 outcomes. Among them, 1-hour pad test leakage (important outcome), the incidence of adverse events (important outcome) are low-quality evidence. ICIQ-SF score (critical outcome) is very low-quality evidence. Compared with PFMT or oral conventional medication, the conventional filiform needling therapy showed small beneficial effects and trivial adverse effects in female UI treatment. Compared with PFMT or oral conventional medication, the conventional filiform needling therapy may be cost-effective and may increase health equity. In addition, the conventional filiform needling therapy is acceptable for patients and doctors, and has good feasibility. The certainty of the evidence body is very low.

(*continued*)

Based on these justifications, the GDG agreed that conventional filiform needling therapy is recommended for the treatment of female UI compared with PFMT or oral conventional medication.
(3) Explanation
• Subgroup The patient population for which this recommendation is developed involved adult female SUI, UUI and MUI. This recommendation is applicable to adult female SUI, UUI and MUI patients. Conventional filiform needling therapy may be recommended when: ① female UI patients who are not resistant to filiform needling therapy; ② especially suitable for female UI patients with poor effect of PFMT; ③ especially suitable for female UI patients with poor effect of oral conventional medication; ④ female UI patients who are concerned about drug side effects. • Implementation Before the implementation of this recommendation, patients are recommended to see a doctor in the department of Urology for the diagnosis and state of UI. Before the implementation of this recommendation, it is recommended to evaluate the necessity of modern medical therapy and the possibility of stopping modern medical therapy. When implementing this recommendation, the consideration of this guide should be fully referred to. • Monitoring and evaluation Monitor whether more female UI patients receive conventional filiform needling therapy after the guidelines are issued rather than PFMT or oral conventional medication. Evaluate the changes in efficacy indicators (frequency of urinary incontinence, quality of life score, urinary incontinence score, etc.), safety indicators (incidence of adverse events, etc.), health economic indicators (incremental cost-benefit ratio, incremental cost effect, incremental cost utility, etc.) and satisfaction with treatment in female UI patients after the implementation of this recommendation.

(*continued*)

• **Research priorities**
To carry out high-quality RCT of conventional filiform needling therapy and modern medical therapy in the treatment of female UI, to explore the effectiveness and non-inferiority, and to evaluate the economic burden of disease and the health economics.
(4) Application of recommendation
Conventional filiform needling therapy may be recommended when: ① female UI patients who do not decline to conventional filiform needling therapy; ② especially suitable for female UI patients with poor effect of PFMT; ③ especially suitable for female UI patients with poor effect of oral conventional medication; ④ female UI patients who are concerned about drug side effects.
(5) Recommended treatment protocol
The specific acupuncture method is conventional filiform needling therapy, displayed in the recommended treating protocol below the recommendations of the first clinical question.

Question 3: On the basis of PFMT or medication treatment, can the combination with conventional filiform needling therapy increase the benefit for moderate-severe female UI patients?
(1) Recommendation
For moderate-severe female UI, PFMT or oral conventional medication combined with conventional filiform needling therapy may be recommended. (Conditional recommendation, low certainty of evidence)
(2) Summary of findings
5 RCTs addressed this clinical question, which is conventional filiform needling therapy and PFMT control, including 5 outcomes. Among them, ICIQ-SF score (critical outcome), IQoL score (critical outcome) are low-quality evidence. Frequency of urinary incontinence in 24 h (critical outcome), 1 hour pad test leakage (important outcome), pelvic floor muscle potential (important outcome) are very low-quality evidence. No RCT studies comparing conventional filiform needling therapy combined with oral conventional medication therapy and oral conventional medication therapy alone were retrieved.

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Compared with PFMT, conventional filiform needling therapy combined with PFMT showed moderate beneficial effects and trivial adverse effects in moderate-severe female UI treatment. Compared with PFMT or oral conventional medication, combined with conventional filiform needling therapy may be cost-effective and may increase health equity. In addition, conventional filiform needling therapy is acceptable for patients and doctors, and has good feasibility. The certainty of the evidence body is low. Based on these justifications, the GDG agreed that PFMT or oral conventional medication combined with conventional filiform needling therapy is recommended for the treatment of moderate-severe female UI.
(3) Explanation
• Subgroup The patient population for which this recommendation is developed involved moderate-severe adult female SUI patients. This recommendation is applicable to moderate-severe adult female SUI patients. For moderate-severe adult female UUI and MUI can also be referred to this recommendation. For following moderate-severe female UI patient groups: ① moderate-severe female UI patients who do not decline to conventional filiform needling therapy; ② especially suitable for moderate-severe female UI patients with poor effect of PFMT; ③ especially suitable for moderate-severe female UI patients with poor effect of oral conventional medication. Relevant contraindications refer to the precautions in the instructions of guideline development. • Implementation Before the implementation of this recommendation, patients are recommended to see a doctor in the department of Urology for the diagnosis and state of UI. The treatment plan for moderate-severe female UI patients should follow the urologist's medical advice. The frequency of conventional filiform needling therapy could be increased or the course of treatment could be prolonged according to the patient's condition and acceptance. When implementing this recommendation, the consideration of this guide should be fully referred to.

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- Monitoring and evaluation

Monitor whether more moderate-severe female UI patients receive PFMT or oral conventional medication combined with conventional filiform needling therapy after the guidelines are issued rather than PFMT or oral conventional medication.

Evaluate the changes in efficacy indicators (frequency of urinary incontinence, quality of life score, urinary incontinence score, etc.), safety indicators (incidence of adverse events, etc.), health economic indicators (incremental cost-benefit ratio, incremental cost effect, incremental cost utility, etc.) and satisfaction with treatment in female UI patients after the implementation of this recommendation.

- Research priorities

To evaluate the efficacy and safety of PFMT or oral conventional medication combined with conventional filiform needling therapy in the treatment of moderate to severe female UI (especially UUI and MUI).

To evaluate the health economics and the economic burden of disease of PFMT or oral conventional medication combined with conventional filiform needling therapy in the treatment of moderate to severe female UI.

(4) Application of recommendation

PFMT or oral conventional medication combined with conventional filiform needling therapy may be recommended when:

① moderate-severe female UI patients who do not decline to conventional filiform needling therapy;

② especially suitable for moderate-severe female UI patients with poor effect of PFMT;

③ especially suitable for moderate-severe female UI patients with poor effect of oral conventional medication.

For female UI patients who are suggested by urologists to receive surgical treatment, the patients should follow the treatment recommendations of specialists.

(5) Recommended treatment protocol

The specific acupuncture method is conventional filiform needling therapy, displayed in the recommended treating protocol below the recommendations of the first clinical question.

For moderate-severe female UI patients, the frequency of treatment could be increased or the course of treatment could be extended according to the patient's condition and acceptance.

Question 4：Compared with no treatment or placebo acupuncture，can female UI patients benefit from the DPSLAT？
（1） Recommendation
For female UI，DPSLAT may be recommended rather than no treatment or placebo acupuncture.（Conditional recommendation，moderate certainty of evidence）
（2） Summary of findings
6 RCTs addressed this clinical question，including 12 outcomes.Among them，frequency of urinary incontinence（three to six months after treatment）（critical outcome），ICIQ-SF score（after treatment）（critical outcome），urine leakage in 1-hour pad test（important outcome），and incidence of adverse events（important outcome）are evidence that is of moderate quality；frequency of urinary incontinence（after treatment）（critical outcome），frequency of urinary incontinence（three months after treatment）（critical outcome），I-QoL score（after treatment）（critical outcome），I-QoL score（3 months after treatment）（critical outcome），ICIQ-SF score（3 months after treatment）（critical outcome），ICIQ-SF score（three to six months after treatment）（critical outcome），urine leakage in 1-hour pad test（three months after treatment）（important outcome）and quantity of pads consumed in 72 hours（important outcome）are evidence that is of low quality. Compared with no treatment or placebo acupuncture，DPSLAT showed moderate beneficial effects and trivial adverse effects in female UI treatment.Compared with no treatment or placebo acupuncture，DPSLAT may be cost-effective and may increase health equity.In addition，DPSLAT is acceptable for patients and doctors，and has good feasibility.The certainty of the evidence body is moderate. Based on these justifications，the GDG agreed that DPSLAT is recommended for the treatment of female UI compared with no treatment or placebo acupuncture.
（3） Explanation
• Subgroup The patient population for which this recommendation is developed involved adult female SUI and MUI.This recommendation is applicable to all types of adult female SUI and MUI patients，and adult female UUI can also be referred to this recommendation. DPSLAT may be recommended the following female UI patient groups： ① female UI patients whose quality of life is impacted by symptoms of urinary incontinence； ② female UI patients who do not decline the treatment of DPSLAT.

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• Implementation Before the implementation of this recommendation, patients are recommended to see a doctor in the department of Urology for the diagnosis and state of UI. When implementing this recommendation, the consideration of this guide should be fully referred to. • Monitoring and evaluation Monitor whether more female UI patients receive DPSLAT after the guidelines are issued. Evaluate the changes in efficacy indicators (frequency of urinary incontinence, quality of life score, urinary incontinence score, etc.), safety indicators (incidence of adverse events, etc.), health economic indicators (incremental cost-benefit ratio, incremental cost effect, incremental cost utility, etc.) and satisfaction with treatment in female UI patients after the implementation of this recommendation. • Research priorities To carry out high-quality RCT between DPSLAT and no treatment/placebo acupuncture for female UUI. Evaluate the efficacy and safety of DPSLAT. Evaluate the efficacy and safety of DPSLAT for special female UI populations (old female UI, minor female UI, etc.). Evaluate the economic burden of disease and the health economics of DPSLAT in treating female UI. Optimize the therapeutic protocol of conventional filiform needling therapy in treating female UI and compare the efficacy, safety, cost-effectiveness and patient preference of different therapeutic protocols.
(4) Application of recommendation
DPSLAT may be recommended when: ① female UI patients whose daily life is impacted by symptoms of urinary incontinence; ② female UI patients who do not decline the treatment of DPSLAT.

(*continued*)

(5) Recommended treatment protocol
• Therapeutic protocol of DPSLAT protocol Ⅰ ① Selection of acupoints Zhongliao (BL33), Huiyang (BL35). ② Operation Body position: the patient is positioned prone with the lumbosacral region adequately exposed. Needles: 0.3 mm × 75 mm disposable acupuncture needles. Acupuncture method: Filiform needling is required at Zhongliao (BL33) with the angle of 30° to 45° in the inward and downward direction. The needling depth ranges from 50 mm to 60 mm. Filiform needling with a direction of outwardly and upwardly oblique angle is appropriate at Hui Yang (BL35). The needling depth would better be 50 mm to 60 mm. Needling manipulation of lifting, inserting and turning is needed to obtain a de-qi sense such as sourness, numbness and swelling. Electroacupuncture electrodes are supposed to be transversely attached to the needle handles of the Zhongliao (BL33) and Hui Yang (BL35) on both sides. It is required to select continuous waves, frequency of 50 Hz and current of 1 to 5 mA were selected. The treatment is expected to last 30 min. ③ Treatment frequency Three times per week. ④ Treatment course Six to eight weeks for mild SUI and MUI. Eight to twelve weeks for moderate-severe SUI and MUI. ⑤ Other issues for patient This protocol is applicable to adult female patients with MUI and SUI. This recommended protocol may also be considered for the treatment of adult female patients with UUI. This protocol may cause strong needle sensation. Patients should be fully explained before clinical practice, and patients who cannot tolerate strong needle sensation should be cautious.

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⑥ Other issues for operation

Users should receive relevant training of this treatment and familiarise themselves with the pertinent anatomical structure before clinical application of this guideline on account of the operational difficulty in this protocol.

Precautions for needles: disposable acupuncture needles with specifications of 0.25 to 0.3 mm × 60 to 75 mm should be determined according to specific conditions considering factors such as body shape, tolerance of female UI patients, etc.

Precautions of acupuncture angles: the acupuncture angle can be adjusted according to specific conditions in order that the needle penetrates through the posterior sacral foramen on the authority of the physiologically structural divergences of female UI patients of different population and races.

Precautions for the application of electroacupuncture: the treatment and parameters of electroacupuncture are meant to be selected according to conditions and acceptance of patients.

Precautions of treatment frequency: owing to the fact that there is some variation in the frequency of acupuncture treatment across the world, the treatment frequency should be at least 1 time/week, 2 to 3 times/week is recommended, depending on the patient's condition, acceptability and other factors as appropriate.

Precautions of course of treatment: owing to the fact that there is some variation in the course of acupuncture treatment across the world, the course of treatment should be at least 6 weeks is a course of treatment, 6 to 12 weeks are recommended, depending on the patient's condition, acceptability and other factors as appropriate.

- Therapeutic protocol of DPSLAT protocol Ⅱ

① Selection of acupoints

Zhibian(BL54).

② Operation

Body position: the patient is positioned prone with the lumbosacral region adequately exposed.

Needles: 0.25 mm × 125 mm disposable acupuncture needles.

(*continued*)

Acupuncture method: The needle is supposed to enter from Zhibian (BL54) and deeply penetrate down for a depth of 110 mm towards Shuidao (ST28). When being inserted, the body of needle is expected to be in a position that forms an angle of 20 degree with the sagittal plane of the trunk and parallel to the horizontal plane of the trunk. The manipulation of needle should not finish until needling sensation (swelling, heating and relaxing) reaches the lower abdomen, anterior genital and perineum. The treatment is expected to last 30 min. ③ Treatment frequency At least 1 time/week, 2 to 3 times/week is recommended, depending on the patient's condition, acceptability and other factors as appropriate. ④ Treatment course At least 2 weeks is a course of treatment, 2 to 4 weeks are recommended, depending on the patient's condition, acceptability and other factors as appropriate. ⑤ Other issues for patient This protocol is applicable to adult female patients with SUI. This recommended protocol may also be considered for the treatment of adult female patients with MUI or UUI. This protocol may cause strong needle sensation. Patients should be fully explained before clinical practice, and patients who cannot tolerate strong needle sensation should be cautious. ⑥ Other issues for operation Users should receive relevant training of this treatment and familiarise themselves with the pertinent anatomical structure before clinical application of this guideline on account of the operational difficulty in this protocol. Precautions of acupuncture depth: The acupuncture depth can be adjusted according to specific conditions, based on Individual differences of the physiologically structural divergences of female UI patients of different population and races.

Question 5:Compared with PFMT or medication treatment,can female UI patients benefit equally or more from the DPSLAT?
(1) Recommendation
For female UI,DPSLAT may be recommended,rather than PFMT or oral conventional medication.(Conditional recommendation,low certainty of evidence)
(2) Summary of findings
9 RCTs addressed this clinical question. There are 3 RCTs of DPSLAT versus PFMT,are integrated in this clinical question,in which urine leakage in 1-hour pad test (after treatment,three months after treatment and three to six months after treatment) is evidence that is of low quality.Frequency of urinary incontinence (after treatment) (critical outcome),ICIQ-SF score (after treatment,three months after treatment and three to six months after treatment) (important outcome),and incidence of adverse events (important outcome) are evidence that is of very low quality. There are 6 RCTs of DPSLAT versus PFMT and oral administration of Solifenacin are included with 3 outcomes involved in this clinical question, in which frequency of urinary incontinence (after treatment,three months after treatment and three to six months after treatment) (critical outcome), urine leakage in 1-hour pad test (after treatment) (important outcome), number of patients in satisfaction (after treatment) (important outcome),and incidence of adverse events (important outcome) are evidence that is of low quality,Incontinence Impact Questionnaire-7 (IIQ-7) (critical outcome), patient satisfaction score (after treatment and three to six months after treatment) and number of patients in satisfaction (three to six months after treatment) are evidence that is of very low quality. Compared with PFMT or oral conventional medication, DPSLAT showed moderate beneficial effects and trivial adverse effects in female UI treatment. Compared with PFMT or oral conventional medication, DPSLAT may be cost-effective and may increase health equity. In addition,DPSLAT is acceptable for patients and doctors,and has good feasibility.The certainty of the evidence body is low. Based on these justifications,the GDG agreed that DPSLAT is recommended for the treatment of female UI compared with PFMT or oral conventional medication.
(3) Explanation
• Subgroup The patient population for which this recommendation is developed involved adult female SUI and MUI.This recommendation is applicable to all types of adult female SUI and MUI patients,and adult female UUI can also be referred to this recommendation.

(*continued*)

DPSLAT may be recommended the following female UI patient groups:

① female UI patients who are not resistant to filiform needling therapy;

② especially suitable for female UI patients with poor effect of PFMT;

③ especially suitable for female UI patients with poor effect of oral conventional medication;

④ female UI patients who are concerned about drug side effects.

- Implementation

Before the implementation of this recommendation, patients are recommended to see a doctor in the department of Urology for the diagnosis and state of UI.

Before the implementation of this recommendation, it is recommended to evaluate the necessity of modern medical therapy and the possibility of stopping modern medical therapy.

When implementing this recommendation, the consideration of this guide should be fully referred to.

- Monitoring and evaluation

Monitor whether more female UI patients receive DPSLAT after the guidelines are issued rather than PFMT or oral conventional medication.

Evaluate the changes in efficacy indicators (frequency of urinary incontinence, quality of life score, urinary incontinence score, etc.), safety indicators (incidence of adverse events, etc.), health economic indicators (incremental cost-benefit ratio, incremental cost effect, incremental cost utility, etc.) and satisfaction with treatment in female UI patients after the implementation of this recommendation.

- Research priorities

To carry out high-quality RCT of DPSLAT and modern medical therapy in the treatment of female UI, to explore the effectiveness and non-inferiority, and to evaluate the economic burden of disease and the health economics.

(*continued*)

(4) Application of recommendation
DPSLAT may be recommended, when: ① female UI patients who do not decline the treatment of DPSLAT; ② especially suitable for female UI patients with poor effect of PFMT; ③ especially suitable for female UI patients with poor effect of oral conventional medication; ④ female UI patients who are concerned about drug side effects.
(5) Recommended treatment protocol
The specific acupuncture method is DPSLAT protocol Ⅰ and Ⅱ, displayed in the recommended treating protocol below the recommendations of the fourth clinical question.

Question 6: On the basis of PFMT or medication treatment, can the combination with the DPSLAT increase the benefit for moderate-severe female UI patients?
(1) Recommendation
For moderate-severe female UI, PFMT or oral conventional medication combined with DPSLAT may be recommended. (Conditional recommendation, very low certainty of evidence)
(2) Summary of findings
3 RCTs addressed this clinical question, all of the 3 RCT are DPSLAT combined with PMFT versus PFMT. 4 outcomes are included in this clinical question. Among them, Incontinence Impact Questionnaire-7 (IIQ-7) (critical outcome), ICIQ-SF score (critical outcome), urine leakage in 1-hour pad test (important outcome), and incidence of adverse events (important outcome) are evidence that is of very low quality. There is no retrieved RCT research of DPSLAT combined with oral conventional medication versus simple oral conventional medication. Compared with PFMT, DPSLAT combined with PFMT showed moderate beneficial effects and trivial adverse effects in moderate-severe female UI treatment. Compared with PFMT or oral conventional medication, combined with DPSLAT may be cost-effective and may increase health equity. In addition, DPSLAT is acceptable for patients and doctors, and has good feasibility. The certainty of the evidence body is very low. Based on these justifications, the GDG agreed that PFMT or oral conventional medication combined with DPSLAT is recommended for the treatment of moderate-severe female UI.

(*continued*)

(3) Explanation
● Subgroup The patient population for which this recommendation is developed involved moderate-severe adult female SUI patients. This recommendation is applicable to moderate-severe adult female SUI patients. For moderate-severe adult female UUI and MUI can also be referred to this recommendation. For following moderate-severe female UI patient groups, PFMT or oral conventional medication combined with DPSLAT is recommended: ① Moderate-severe female UI patients who do not decline to DPSLAT; ② Especially suitable for moderate-severe female UI patients with poor effect of PFMT; ③ Especially suitable for moderate-severe female UI patients with poor effect of oral conventional medication. For female UI patients whose condition is assessed by urologists and requires surgery, acupuncture should be used with caution, in accordance with the treatment recommendations of specialists. ● Implementation Before the implementation of this recommendation, patients are recommended to see a doctor in the department of Urology for the diagnosis and state of UI. The treatment plan for moderate-severe female UI patients should follow the urologist's medical advice. The frequency of DPSLAT could be increased or the course of treatment could be prolonged according to the patient's condition and acceptance. When implementing this recommendation, the consideration of this guide should be fully referred to. ● Monitoring and evaluation Monitor whether more moderate-severe female UI patients receive PFMT or oral conventional medication combined with DPSLAT after the guidelines are issued. Evaluate the changes in efficacy indicators (frequency of urinary incontinence, quality of life score, urinary incontinence score, etc.), safety indicators (incidence of adverse events, etc.), health economic indicators (incremental cost-benefit ratio, incremental cost effect, incremental cost utility, etc.) and satisfaction with treatment in female UI patients after the implementation of this recommendation.

(*continued*)

• Research priorities To evaluate the efficacy, safety, health economics and economic burden of disease, of PFMT or oral conventional medication combined with DPSLAT in the treatment of moderate to severe female UI (especially UUI and MUI).
(4) Application of recommendation
PFMT or oral conventional medication combined with DPSLAT may be recommended, when: ① moderate-severe female UI patients who do not decline to DPSLAT; ② especially suitable for moderate-severe female UI patients with poor effect of PFMT; ③ especially suitable for moderate-severe female UI patients with poor effect of oral conventional medication. For female UI patients who are suggested by urologists to receive surgical treatment, the patients should follow the treatment recommendations of specialists.
(5) Recommended treatment protocol
The specific acupuncture method is DPSLAT protocol Ⅰ and Ⅱ, displayed in the recommended treating protocol below the recommendations of the fourth clinical question. For moderate-severe female UI patients, the frequency of treatment could be increased or the course of treatment could be extended according to the patient's condition and acceptance.

Question 7: Compared with no treatment, can female urinary incontinence (UI) patients benefit from moxibustion therapy?
(1) Recommendation
For female UI, moxibustion therapy may be recommended, rather than no treatment. (Conditional recommendation, very low certainty of evidence)
(2) Summary of findings
4 case series studies of moxibustion for female UI and 9 RCTs of moxibustion for post-stroke urinary incontinence were included as supplementary evidence for this clinical question, involving 7 outcomes. Among them, the frequency of urinary incontinence in 24 h (critical outcome), IQoL score (critical outcome), ICIQ-SF score (critical outcome), 1-hour pad test leakage (important outcome), and incidence of adverse events (important outcome) were very low-quality evidence.

(*continued*)

Compared with no treatment, moxibustion therapy for female UI showed a moderate beneficial effect and a trivial adverse effect. Based on these justifications, the GDG agreed that moxibustion therapy can be recommended for the treatment of female UI.
(3) Explanation
• Subgroup The patient population for which this recommendation is developed involved adult female SUI. This recommendation is applicable to all types of adult female SUI patients, and adult female UUI and MUI can also be referred to this recommendation. For following female UI patient groups, moxibustion therapy is recommended: ① female UI patients who do not decline moxibustion treatment; ② female UI patients whose quality of life is impacted by symptoms of UI; ③ especially suitable for postpartum UI and elderly female UI patients; ④ especially suitable for female urinary incontinence patients diagnosed with TCM syndrome of deficiency. • Implementation Before the implementation of this recommendation, patients are recommended to see a doctor in the department of Urology for the diagnosis and state of UI. When implementing this recommendation, the consideration of this guide should be fully referred to. • Monitoring and evaluation Monitor whether more female UI patients receive moxibustion therapy after the guidelines are issued. Evaluate the changes in efficacy indicators (frequency of urinary incontinence, quality of life score, urinary incontinence score, etc.), safety indicators (incidence of adverse events, etc.), health economic indicators (incremental cost-benefit ratio, incremental cost effect, incremental cost utility, etc.) and satisfaction with treatment in female UI patients after the implementation of this recommendation.

(*continued*)

• Research priorities To carry out high-quality RCT between moxibustion therapy and no treatment for female UI. Evaluate the efficacy and safety of moxibustion therapy. Evaluate the economic burden of disease and the health economics of moxibustion therapy in treating female UI. Evaluate the efficacy and safety of moxibustion therapy for special female UI populations (old female UI, minor female UI, etc.).
(4) Application of recommendation
Moxibustion therapy may be recommended, when: ① female UI patients who do not decline moxibustion treatment; ② female UI patients whose quality of life is impacted by symptoms of UI; ③ especially suitable for postpartum UI and elderly female UI patients; ④ especially suitable for female urinary incontinence patients diagnosed with TCM syndrome of deficiency.
(5) Recommended treatment protocol
• Moxibustion protocol Ⅰ: suspended moxibustion ① Selection of acupoints Guanyuan (CV4), Qihai (CV6), Shenshu (BL23), Ciliao (BL32), select acupoints according to the patient's condition. ② Operation The treatment is carried out by suspension moxibustion method, so that the patient has a local warmth of acupoints without burning pain is appropriate, according to the patient's condition and tolerance, determine the treatment duration as appropriate. In clinical treatment, the acupoints within the abdomen and lumbosacral region can be treated simultaneously with the application of moxibustion with a moxa burn where necessary to shorten the length of treatment and save human resources.

(*continued*)

- Moxibustion protocol Ⅱ: warming needling moxibustion

① Selection of acupoints

Zhongji(CV3), Qihai(CV6), Guanyuan(CV4), Shenshu(BL23), Ciliao(BL32), Zusanli(ST36), select acupoints according to the patient's condition.

② Operation

Warming needle moxibustion is used for treatment, and the duration of treatment is determined according to the patient's condition and tolerance as appropriate.

- Moxibustion protocol Ⅲ: indirect moxibustion

① Selection of acupoints

Zhongji(CV3), Guanyuan (CV4), Qihai (CV6), Shenque (CV8), Shenshu (BL23), Pangguangshu (BL28), Guanyuanshu(BL26), select acupoints according to the patient's condition.

② Internal drugs

Ginger slices: make 2 to 3 cm diameter, 0.2 to 0.3 cm thick slices of ginger, with several holes poked in the middle.

Herbal cake: Choose one or more kinds of Chinese herbs [e.g. Radix Aconiti Lateralis Praeparata (monkshood, fù zǐ), Cortex Cinnamomi (cassia bark, ròu guì), Ramulus Cinnamomi (cassia twig, guì zhī)] with property of warming Yang, grind them into fine powder, and mix them with ginger juice.

③ Operation

Indirect moxibustion is used for treatment, and the duration of treatment is determined according to the patient's condition and tolerance as appropriate.

- Moxibustion protocol Ⅳ: warming needling moxibustion

① Selection of acupoints

Look for heat-sensitive points around the Qihai(CV6), Zhongji (CV3), Guanyuan (CV4), Shenshu (BL23), Pangguangshu(BL28), Ciliao(BL32), Sanyinjiao(SP6), and Baihui(GV20).

(*continued*)

② Operation Heat sensitive moxibustion is used for treatment, and the duration of treatment is determined according to the patient's condition and tolerance as appropriate. • **Treatment frequency of moxibustion treatment** At least 1 time/week, 2 to 3 times/week is recommended, depending on the patient's condition, acceptability and other factors as appropriate. • **Treatment course of moxibustion treatment** 4 weeks is a course of treatment, and 1 to 2 courses are recommended, depending on the patient's condition, acceptability and other factors as appropriate. • **Other issues of moxibustion treatment** ① moxibustion treatment is prohibited for those who are allergic to moxibustion materials; ② moxibustion should not be used for those who cannot tolerate the smoke produced during the application of moxibustion; ③ warming needle treatment, indirect moxibustion, and heat sensitive moxibustion have certain operational requirements, and the applicators should receive relevant training.

Question 8: Compared with PFMT or medication treatment, can female UI patients benefit equally or more from moxibustion therapy?
(1) Recommendation
For female UI patients, moxibustion therapy, PFMT or oral conventional medication may be recommended. (Conditional recommendation towards intervention or comparison, very low certainty of evidence)
(2) Summary of findings
1 RCTs addressed this clinical question. There is 1 RCT of moxibustion treatment versus pelvic floor muscle function training, involving 3 outcomes. Among them, ICIQ-SF (after trreatment) (critical outcome), ICIQ-SF (3 to 6 months follow-up) (critical outcome), adverse events (important outcomes) are very low quality evidence.

(*continued*)

No RCTs of moxibustion treatment versus oral conventional medication were searched. Compared with pelvic floor muscle training, moxibustion therapy for female UI showed a trivial beneficial effect and a trivial adverse effect. Compared to pelvic floor muscle training or oral conventional medication, moxibustion for female UI may be equally cost effective and may increase health equity. In addition, moxibustion treatment is more easily accepted by patients and physicians and has the feasibility. The credibility of the relevant evidence is very low. Based on these justifications, the GDG agreed that moxibustion therapy or pelvic floor muscle training or oral conventional medication can be recommended for the treatment of female UI patients.
(3) Explanation
• Subgroup The patient population for which this recommendation is developed involved adult female SUI. This recommendation is applicable to all types of adult female SUI patients, and adult female UUI and MUI can also be referred to this recommendation. Subject to the diagnosis and treatment plan of the urologist, the use of moxibustion is recommended for the following groups of female UI patients: ① female UI patients who wish to receive moxibustion therapy; ② postpartum UI and elderly female UI patients; ③ female urinary incontinence patients diagnosed with TCM syndrome of deficiency. • Implementation Before the implementation of this recommendation, patients are recommended to see a doctor in the department of Urology for the diagnosis and state of UI. Before the implementation of this recommendation, it is recommended to evaluate the necessity of modern medical therapy and the possibility of stopping modern medical therapy. When implementing this recommendation, the consideration of this guide should be fully referred to. • Monitoring and evaluation Monitor whether more female UI patients receive moxibustion therapy after the guidelines are issued.

(*continued*)

Evaluate the changes in efficacy indicators (frequency of urinary incontinence, quality of life score, urinary incontinence score, etc.), safety indicators (incidence of adverse events, etc.), health economic indicators (incremental cost-benefit ratio, incremental cost effect, incremental cost utility, etc.) and satisfaction with treatment in female UI patients after the implementation of this recommendation. • **Research priorities** To carry out high-quality RCT of moxibustion therapy and modern medical therapy in the treatment of female UI, to explore the effectiveness and non-inferiority, and to evaluate the economic burden of disease and the health economics.
(**4**) **Application of recommendation**
Moxibustion therapy may be recommended, when: ① female UI patients who wish to receive moxibustion therapy; ② postpartum UI and elderly female UI patients; ③ female urinary incontinence patients diagnosed with TCM syndrome of deficiency. PMFT may be recommended, when: female UI patients who are recommended to accept PMFT first after assessment of their condition by a urologist. Oral conventional medication may be recommended, when: female UI patients who are recommended to accept oral conventional medication first after assessment of their condition by a urologist.
(**5**) **Recommended treatment protocol**
The specific moxibustion method is suspended moxibustion, warming needle moxibustion, indirect moxibustion and heat sensitive moxibustion displayed in the recommended treating protocol below the recommendations of the seventh clinical question.

Question 9: On the basis of PFMT or medication treatment, can the combination with moxibustion therapy increase the benefit for moderate-severe female UI patients?
(**1**) **Recommendation**
For moderate-severe female UI, PFMT or oral conventional medication combined with moxibustion therapy may be recommended. (Conditional recommendation, very low certainty of evidence)

(*continued*)

(2) Summary of findings
18 RCTs addressed this clinical question. There are 17 RCTs of moxibustion treatment combined with PMFT versus PMFT, involving 10 outcomes. Among them, the frequency of urinary incontinence(after treatment, follow-up within 3 months)(critical outcome), quality of life score (IQoL、GQOLI-74)(critical outcome), ICIQ-SF (after trreatment, follow-up within 3 months) (critical outcome), urine leakage in 24 h(after trreatment, follow-up within 3 months) (important outcomes), 1-hour pad test leakage(after treatment, follow-up within 3 months) (important outcomes), urodynamic examination-average flow rate (important outcomes), adverse events (important outcomes) are very low quality evidence. There is 1 RCT of moxibustion treatment combined with oral medication versus oral medication, involved 3 outcomes, of which the number of incontinence (after treatment) (critical outcome), urodynamic examination-maximum flow rate, and average flow rate (important outcome) were all very low quality evidence. Compared with PFMT or oral conventional medication treatment alone, the combined application of moxibustion for moderate to severe female UI showed a moderate beneficial effect and a trivial adverse effect. Compared with PFMT or oral conventional medication treatment alone, the combined application of moxibustion for the treatment of moderate to severe female UI may be more cost-effective, more acceptable to patients and physicians, feasible, and may increase health equity. The credibility of the relevant evidence is very low. Based on these justifications, the GDG agreed that the combination of moxibustion with pelvic floor muscle training or oral conventional medication can be recommended for the treatment of moderate to severe female UI compared to pelvic floor muscle training or oral conventional medication alone.
(3) Explanation
• Subgroup The patient population for which this recommendation is developed involved moderate-severe adult female SUI patients. This recommendation is applicable to moderate-severe adult female SUI patients. For moderate-severe adult female UUI and MUI can also be referred to this recommendation. PFMT or oral conventional medication combined with moxibustion therapy is recommended in the treatment of female UI patient groups as follows: ① moderate-severe female UI patients who do not decline to moxibustion therapy; ② especially suitable for moderate-severe female UI patients with poor effect of PFMT;

(*continued*)

③ especially suitable for moderate-severe female UI patients with poor effect of oral conventional medication. • Implementation Before the implementation of this recommendation, patients are recommended to see a doctor in the department of Urology for the diagnosis and state of UI. The treatment plan for moderate-severe female UI patients should follow the urologist's medical advice. The frequency of moxibustion therapy could be increased or the course of treatment could be prolonged according to the patient's condition and acceptance. When implementing this recommendation, the consideration of this guide should be fully referred to. • Monitoring and evaluation Monitor whether more moderate-severe female UI patients receive PFMT or oral conventional medication combined with moxibustion therapy after the guidelines are issued rather than PFMT or oral conventional medication. Evaluate the changes in efficacy indicators (frequency of urinary incontinence, quality of life score, urinary incontinence score, etc.), safety indicators (incidence of adverse events, etc.), health economic indicators (incremental cost-benefit ratio, incremental cost effect, incremental cost utility, etc.) and satisfaction with treatment in female UI patients after the implementation of this recommendation. • Research priorities To evaluate the efficacy, safety, health economics and economic burden of disease, of PFMT or oral conventional medication combined with moxibustion therapy in the treatment of moderate to severe female UI (especially UUI and MUI).
(4) Application of recommendation
PFMT or oral conventional medication combined with moxibustion therapy may be recommended, when: ① moderate-severe female UI patients who do not decline to moxibustion therapy; ② especially suitable for moderate-severe female UI patients with poor effect of PFMT; ③ especially suitable for moderate-severe female UI patients with poor effect of oral conventional medication.

(*continued*)

For female UI patients who are suggested by urologists to receive surgical treatment, the patients should follow the treatment recommendations of specialists.
(5) Recommended treatment protocol
The specific moxibustion method is suspended moxibustion, warming needle moxibustion, indirect moxibustion and heat sensitive moxibustion displayed in the recommended treating protocol below the recommendations of the seventh clinical question. For moderate-severe female UI patients, the frequency of treatment could be increased or the course of treatment could be extended according to the patient's condition and acceptance.

Question 10: Compared with filiform needling therapy or moxibustion therapy alone, does the combination of filiform needling and moxibustion therapy increase the benefit for female UI patients?
(1) Recommendation
For female UI patients, the combination of filiform needling and moxibustion therapy may be recommended. (Conditional recommendation, very low certainty of evidence)
(2) Summary of findings
6 RCTs addressed this clinical question, including 7 outcomes. Among them, the frequency of urinary incontinence (critical outcome) and residual urine ultrasound-bladder residual urine volume (important outcomes) are low quality evidence. ICIQ-SF (critical outcome) and 1-hour pad test leakage (important outcomes) are very low quality evidence. Compared with filiform needling therapy or moxibustion therapy alone, the combination of the two treatments shows a moderate beneficial effect and a trivial adverse effect. Compared to acupuncture or moxibustion treatment alone, acupuncture combined with moxibustion for female UI may have better cost-effectiveness and may increase health equity. In addition, acupuncture combined with moxibustion treatment is easily accepted by patients and physicians and has good feasibility. The credibility of the relevant evidence is low.
(3) Explanation
• Subgroup The patient population for which this recommendation is developed involved adult female SUI and MUI patients. This recommendation is applicable to adult female SUI and MUI patients. For adult female UUI could also be referred to this recommendation.

(*continued*)

• Implementation Before the implementation of this recommendation, patients are recommended to see a doctor in the department of Urology for the diagnosis and state of UI. When implementing this recommendation, the consideration of this guide should be fully referred to. • Monitoring and evaluation Monitor whether more female UI patients receive the combination of filiform needling and moxibustion therapy after the guidelines are issued. Evaluate the changes in efficacy indicators (frequency of urinary incontinence, quality of life score, urinary incontinence score, etc.), safety indicators (incidence of adverse events, etc.), health economic indicators (incremental cost-benefit ratio, incremental cost effect, incremental cost utility, etc.) and satisfaction with treatment in female UI patients after the implementation of this recommendation. • Research priorities Carry out high-quality RCT of acupuncture treatment combined with moxibustion therapy and modern medical therapy control in the treatment of female UI. Explore the effectiveness and non-inferiority research. Evaluate the economic burden of disease, the health economics and patients' preference.
(4) Application of recommendation
For female UI patients with poor effect of filiform needling therapy alone or simple moxibustion, filiform needling combined with moxibustion may be recommended.
(5) Recommended treatment protocol
The specific acupuncture method is conventional filiform needling therapy, DPSLAT therapeutic schedule Ⅰ and schedule Ⅱ, displayed in the recommended treating protocol below the recommendations of the first and fourth clinical question. The specific moxibustion method is suspended moxibustion, warming needling, indirect moxibustion and heat sensitive moxibustion displayed in the recommended treating protocol below the recommendations of the seventh clinical question.

5 Access to the guideline

This guide is published on the website of the World Federation of Acupuncture-Moxibustion Societies.The paper version is published by Standards Press of China.In addition, the core content of the guide will be published in English journals.Users can obtain this guide through the above access.

6 Implication for future research

The future research priorities are shown in research priorities in recommendation Table.

7 Limitations

According to the clinical questions survey of target users, the clinical questions and recommendations of this guideline mainly focus on the interventions (filiform needle acupuncture and moxibustion) that elicited the most interest.Other types of acupuncture therapies for female UI (acupoint application, auricular point stimulation, etc.) are not involved in this edition.

8 Consideration

8.1 Notes on laws and regulations

Users of the guidelines need to use acupuncture therapy for female UI on the premise of complying with the laws and regulations of the country/region.

8.2 Notes for medical institutions

8.2.1 Medical institutions should be qualified for acupuncture and moxibustion therapy.

8.2.2 Medical institutions should have rescue facilities and drugs that can deal with adverse events related to acupuncture and moxibustion.

8.2.3 For moxibustion treatment, it is suggested that medical institutions should set up special moxibustion rooms, equipped with exhaust fans and fire prevention facilities.

8.3 Notes for doctors

8.3.1 Qualified acupuncture and moxibustion practitioners are required.

8.3.2 Before acupuncture treatment, doctors should fully explain the possible benefits and potential risks of relevant acupuncture and moxibustion treatment programs to patients, and then carry out treatment after obtaining the consent of patients.

8.3.3 Doctors should prevent the occurrence of adverse events (such as needle fainting, traumatic pneumothorax, stabbing organs, scald, etc.) and have the ability to deal with acupuncture related adverse events.

8.4 What needs to be clear to the patient

In the following cases, special attention should be paid to the use of acupuncture and moxibustion.

8.4.1 Acupuncture is not suitable for patients with fasting, over satiety, extreme fatigue and fear of acupuncture therapy. For patients with thin body, acupuncture manipulation should not be too strong.

8.4.2 For pregnant women, it is not suitable to stimulate acupoints in the abdominal and lumbosacral regions, and the acupoints with strong function of dredging meridians and activating blood circulation (such as Hegu, Sanyinjiao, etc.).

8.4.3 For patients with bleeding tendency, acupuncture should be used cautiously.

8.4.4 For patients with skin infection, ulcer or tumor at acupoints, acupuncture should be used cautiously.

8.4.5 Moxibustion should be carried out in a ventilated environment to prevent burning moxa floss from falling off and burning skin and clothing.

Annex A
Members of guideline working group

A.1 Guideline development group (GDG) members (In random order)

Name	Country	Specialty	Role/identity	Affiliation
Ye-meng Chen	U.S.	Acupuncture and moxibustion	Expert in acupuncture and moxibustion	New York College of Traditional Chinese Medicine
Han-wen Deng	Australia	Acupuncture and moxibustion	Expert in acupuncture and moxibustion	Sydney Institute of Traditional Chinese Medicine
Xiao-ming Wang	Japan	Acupuncture and moxibustion	Expert in acupuncture and moxibustion	Teikyo Heisei University
Hong-guang Dong	Switzerland	Acupuncture and moxibustion	Expert in acupuncture and moxibustion	University of Geneva
Yue-lai Chen	China	Acupuncture and moxibustion	Expert in acupuncture and moxibustion	Longhua Hospital Affiliated to Shanghai University of Traditional Chinese Medicine
Zhao-yu Dai	China	Acupuncture and moxibustion	Expert in acupuncture and moxibustion	Hong Kong Baptist University
Chun-sheng Jia	China	Acupuncture and moxibustion	Expert in acupuncture and moxibustion	Hebei University of Chinese Medicine
Jing-sheng Zhao	China	Acupuncture and moxibustion	Expert in acupuncture and moxibustion	Institute of Acupuncture and Moxibustion, China Academy of Chinese Medical Sciences
Hao-ran Chu	China	Acupuncture and moxibustion	Expert in acupuncture and moxibustion	The Second Affiliated Hospital of Anhui University of Chinese Medicine
Lai-xi Ji	China	Acupuncture and moxibustion	Expert in acupuncture and moxibustion	Shanxi University of Chinese Medicine
Zhuo-xin Yang	China	Acupuncture and moxibustion	Expert in acupuncture and moxibustion	Shenzhen Traditional Chinese Medicine Hospital

(*continued*)

Name	Country	Specialty	Role/identity	Affiliation
Xue-mei Cao	China	Otolaryngology/ TCM	Experts in postpartum recovery	Shenzhen Traditional Chinese Medicine Hospital
Yong-ji Yan	China	Otolaryngology	Experts in urology	Dongzhimen Hospital, Beijing University of Chinese Medicine
Jian-ping Liu	China	Evidence based medicine	Expert in methodology	Beijing University of Chinese Medicine
Yu-tong Fei	China	Evidence based medicine	Expert in methodology	Beijing University of Chinese Medicine
Bao-lin Hong	China	Health economist	Expert in health economist	Beijing University of Chinese Medicine
Ms. Yang	China	—	Female urinary incontinence patient	—

A.2 Guideline drafting group members

Name	Specialty	Affiliation
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Chao Yang	Acupuncture and moxibustion	Dongzhimen Hospital, Beijing University of Chinese Medicine
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Shan-ze Wang	Acupuncture and moxibustion	Dongzhimen Hospital, Beijing University of Chinese Medicine

Annex B
Abbreviations

Full name	Abbreviation
abdominal leak point pressure	ALPP
Clinical Practice Guideline	CPG
Deep Puncturing Stimulation on Lumbosacral Acupoints Therapy	DPSLAT
European Association of Urology	EAU
Evidence to Decision	EtD
Grading of Recommendations Assessment, Development and Evaluation	GRADE
Guideline Development Group	GDG
International Continence Society	ICS
maximum urethral closure pressure	MUCP
mixed urinary incontinence	MUI
urinary incontinence	UI
urge urinary incontinence	UUI
patient, intervention, comparison, outcome	PICO
randomized controlled trial	RCT
stress urinary incontinence	SUI
World Health Organization	WHO
World Federation of Acupuncture-Moxibustion Societies	WFAS

Annex C
Summary of clinical questions

No.	Clinical Questions
1	Compared with no treatment or placebo acupuncture, can female UI patients benefit from conventional filiform needling therapy?
2	Compared with PFMT or medication treatment, can female UI patients benefit equally or more from conventional filiform needling therapy?
3	On the basis of PFMT or medication treatment, can the combination with conventional filiform needling therapy increase the benefit for moderate-severe female UI patients?
4	Compared with no treatment or placebo acupuncture, can female UI patients benefit from the DPSLAT?
5	Compared with PFMT or medication treatment, can female UI patients benefit equally or more from the DPSLAT?
6	On the basis of PFMT or medication treatment, can the combination with the DPSLAT increase the benefit for moderate-severe female UI patients?
7	Compared with no treatment, can female urinary incontinence (UI) patients benefit from moxibustion therapy?
8	Compared with PFMT or medication treatment, can female UI patients benefit equally or more from moxibustion therapy?
9	On the basis of PFMT or medication treatment, can the combination with moxibustion therapy increase the benefit for moderate-severe female UI patients?
10	Compared with filiform needling therapy or moxibustion therapy alone, does the combination of filiform needling and moxibustion therapy increase the benefit for female UI patients?

前　　言

本指南的制定旨在为女性尿失禁的临床治疗提供针灸推荐意见及施术方案。

本指南依据世界针灸学会联合会标准工作委员会制定的技术流程和规则研制。

本指南由世界针灸学会联合会(World Federation of Acupuncture-Moxibustion Societies,WFAS)归口并发布。

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本指南的制定得到了中华人民共和国科技部-国家重点研发计划中医药现代化研究重点专项项目国际针灸临床实践指南、技术操作规范和服务标准的研制(项目编号:2019YFC1712200)中国际针灸临床实践指南研制课题(课题编号:2019YFC1712203)的基金支持。

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请注意本指南的某些内容可能涉及专利。本指南的发布机构不承担识别专利的责任。

针灸临床实践指南
女性尿失禁

1 指南概要

1.1 名词术语

1.1.1

常规毫针治疗

本指南中的常规毫针治疗是指:根据传统的针灸辨证论治理论,以任脉穴、足太阴经穴、膀胱的俞募穴等为主穴,以毫针刺法为主要干预措施,针刺常规深度,可配合电针等增强针感的干预措施,用以治疗女性尿失禁的一类毫针刺疗法的总称。

1.1.2

毫针深刺腰骶部腧穴治疗

本指南中的毫针深刺腰骶部腧穴治疗(Deep Puncturing Stimulation in Lumbosacral Acupoints Therapy,DPSLAT)是指:以长毫针为针刺工具,针刺腰骶部相关腧穴(如八髎、会阳、秩边等),针刺深度在 50 mm 及以上深度,可配合电针法等增强针感的干预措施,针刺后以较强的会阴放射感、阴部下坠感为得气感受的一类毫针刺疗法的总称。

1.1.3

艾灸治疗

本指南中的艾灸治疗是指:以艾为主要灸材,以艾条灸法、艾炷灸法、温针灸法为主要干预手段,在体表的一定部位或穴位进行烧灼、温熨,以治疗疾病的一类灸疗法的总称。本指南中涉及的艾灸治疗主要分为:悬起灸治疗、温针灸治疗、隔物灸治疗、热敏灸治疗。

悬起灸治疗的主要操作:将艾条的一端点燃,对准应灸的腧穴或患处,距离皮肤 2 cm～3 cm 处进行熏灼,可分为温和灸、雀啄灸及回旋灸 3 种,一般每次治疗灸至皮肤潮红为度。

温针灸治疗的主要操作:将针刺入腧穴,得气后并给予适当补泻手法,在留针时,将纯净细软的艾绒捏在针尾上,或将艾条(截取长度 2 cm 左右的艾条段)插在针柄上,点燃施灸,待艾绒或艾条烧完后除去灰烬,将针起出。

隔物灸治疗的主要操作:在艾炷与皮肤之间垫隔上某物品而施灸,治疗女性尿失禁的隔物灸治疗,间隔物可选取生姜或具有温通作用的中药药泥。

热敏灸治疗的主要操作:施灸前先寻找热敏点,选用特制的灸条对热敏点施灸,直至热敏现象消失,艾灸热敏点所发生的透热、传热感,可以激发经气感传,使气至病所。

1.1.4

盆底肌功能训练

盆底肌功能训练(Pelvic Floor Muscle Training,PFMT)可作为压力性尿失禁(Stress Urinary Incontinence,SUI)、急迫性尿失禁(Urge Urinary Incontinence,UUI)、混合性尿失禁(Mixed Urinary Incontinence,MUI)的有效方法。目前对于盆底肌肉的康复训练包括凯格尔运动、盆底肌电刺激治疗、生物反馈治疗等。其中凯格尔运动是最常用的盆底肌功能训练,主要操作如下:持续盆底肌肉收缩(肛门收缩运动)不少于 3 s,放松休息 2 s～6 s,重复以上动作 15 min～30 min,或者每日做 150 次～200 次

肛门收缩运动，训练3个月后门诊评估病情。

1.1.5

尿失禁的药物治疗

当前基于证据的尿失禁药物治疗主要用于急迫性尿失禁UUI的备用治疗。临床常用于治疗UUI的药物包括抗胆碱药(如索利那新、托特罗定)、β3肾上腺素受体激动剂(如米拉贝隆)。

1.2 目的

WFAS《针灸临床实践指南　女性尿失禁》(以下简称本指南)的编写目的在于根据现有临床证据，针对目前针灸治疗女性尿失禁的国际需求及关注的临床问题，在充分考虑国际适用性的基础上，结合尿失禁患者的价值观和意愿，系统研制出帮助临床医生和患者作出恰当针灸处理的指导性意见。本指南将致力于提高女性尿失禁针灸治疗技术的有效性、安全性与规范性，促进针灸治疗女性尿失禁在国际范围内的临床应用推广。

1.3 范围

本指南的适用疾病范围为女性尿失禁，各种类型、不同程度的女性尿失禁均可以酌情采用针灸治疗。本指南的适用患者为成人女性尿失禁患者。

1.4 适用人群

本指南的目标人群为全球范围内与女性尿失禁临床、教学和科研相关的专业人员，包括：①针灸医师；②中医医师；③泌尿科医师；④医学院或中医教育培训机构的教师和学生；⑤中医药科研机构相关人员。

1.5 适用场所

本指南的适用环境为全球范围内包含针灸专科的医院、从事针灸学临床工作的基层医院或诊所、包含针灸学专业的医学院校、针灸学相关的科研及评价机构。

1.6 推荐意见汇总

编号	推荐意见	推荐级别	证据质量
1	对于女性UI患者，可以推荐采用常规毫针治疗，而非不治疗或安慰针刺。	条件性推荐	低
2	对于女性UI患者，相比于盆底肌功能训练或口服药物，可以推荐常规毫针治疗。	条件性推荐	极低
3	对于中重度女性UI患者，可以推荐在盆底肌功能训练或口服药物的基础上联合常规毫针治疗。	条件性推荐	低
4	对于女性UI患者，可以推荐毫针深刺腰骶部腧穴治疗(DPSLAT)，而非不治疗或安慰针刺。	条件性推荐	中
5	对于女性UI患者，相比于盆底肌功能训练或口服药物，可以推荐DPSLAT。	条件性推荐	低

（续）

编号	推荐意见	推荐级别	证据质量
6	对于中重度女性 UI 患者，可以推荐在盆底肌功能训练或口服药物的基础上联合 DPSLAT。	条件性推荐	极低
7	对于女性 UI 患者，可以推荐艾灸治疗，而非不治疗。	条件性推荐	极低
8	对于女性 UI 患者，可以推荐艾灸治疗或盆底肌功能训练或口服药物治疗。	条件性推荐干预或对照	极低
9	对于中重度女性 UI 患者，可以推荐在盆底肌功能训练或口服药物的基础上联合艾灸治疗。	条件性推荐	极低
10	对于女性 UI 患者，可以推荐毫针联合艾灸治疗。	条件性推荐	极低

1.7　联系人

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2　疾病概述

2.1　现代医学定义

国际尿控协会（International Continence Society，ICS）将不能由意志控制的经尿道漏尿定义为尿失禁（Urinary Incontinence，UI）。欧洲泌尿外科学会（European Association of Urology，EAU）将尿失禁分为压力性尿失禁（Stress Urinary Incontinence，SUI）、混合性尿失禁（Mixed Urinary Incontinence，MUI）及急迫性尿失禁（Urge Urinary Incontinence，UUI）[1]。SUI 是指腹压增加（咳嗽、大笑、喷嚏及运动）时出现不自主的尿液流出。UUI 是指有尿意时即急不可待，往往来不及到厕所即出现漏尿症状。MUI 是指压力性尿失禁和急迫性尿失禁同时存在，并伴有膀胱括约肌功能不全者。

2.2　流行病学特征

澳大利亚的流行病学调查[2]发现 36.2％的澳大利亚女性受尿失禁困扰，其中混合性尿失禁最为常见，患病率为 14.6％，其次为急迫性尿失禁（11.3％），而压力性尿失禁的患病率只有 10.4％。在中国女性人群中，尿失禁的发病率为 18.9％，并随年龄增长而增加，其中 50 岁～59 岁是压力性尿失禁患病的高峰年龄（28.2％）[3]。在美国，女性尿失禁的患病率约为 17.1％，每年因尿失禁问题投入医疗费用高达 300 亿美元[4]。

尿失禁虽然不会对患者的生命构成威胁，但对患者的日常行为和心理及社会交往影响较大，使患者感到沮丧、无助和焦虑，女性患者尤为明显，严重影响女性患者的生活质量，被称为“不致命的社交癌症”。

2.3　症状、体征和检查

2.3.1　症状

2.3.1.1　SUI：根据患者的主观症状轻重，对于压力性尿失禁可进行如下分度：①轻度：漏尿发生在咳嗽、打喷嚏时，不需要使用尿垫；②中度：漏尿发生在跑跳、快步行走等日常活动时，需要使用尿垫；③重

度:轻微活动、体位改变就发生漏尿,需要使用尿垫。

2.3.1.2 UUI:主要症状为尿急、尿频、夜尿和不能自主控制排尿。在有尿意感后立即发生的尿液不自主漏出,受活动及环境,如流水声、寒冷刺激等诱发。

2.3.1.3 MUI:同时具有 SUI 和 UUI 的症状。

2.3.2 体征

体格检查的重点在于检查是否存在导致尿失禁的病因,有利于治疗方式的选择,尿失禁患者的体格检查主要包括一般检查、会阴/生殖器检查、神经系统检查以及特殊检查 4 个部分。

2.3.2.1 一般检查

身高、体重及 BMI 指数均与尿失禁的发病有明确的相关性,一般检查同时需要注意腹部有无手术瘢痕、有无腹部和腹股沟疝,骶尾部皮肤有无凹陷、隆起等异常,下腹部有无膨胀的膀胱及膀胱充盈程度,有无脊柱发育畸形等。

2.3.2.2 会阴/生殖器检查

怀疑存在压力性尿失禁时,患者处膀胱截石位,膀胱适度充盈,嘱患者做咳嗽或增加腹压动作时,观察是否同时有尿液自尿道不自主流出,证实是否存在压力性尿失禁,女性压力性尿失禁患者还要评价膀胱颈的移动性,尤其当咳嗽或增加腹压时是否有盆底器官脱垂,评价盆底肌功能及患者进行盆底肌收缩的能力。

2.3.2.3 神经系统检查

尿失禁患者神经系统检查的目的主要是排除神经学病因引起的尿失禁。详细的神经系统检查包括精神状态、感觉功能、反射完整性,对于尿失禁患者的神经系统检查重点在骶尾部的检查,包括双下肢的感觉运动、会阴区的感觉运动等,临床上一般以肛门括约肌的功能来评估尿道外括约肌的功能。最常用的反射是轻触肛门黏膜皮肤交界处可以引起肛门外括约肌收缩,称为肛门反射,若该反射消失常提示骶神经损伤。肛门的自主收缩检查有助于判断盆底肌肉神经支配,球海绵体反射可以反映骶髓的局部反射,该反射消失提示骶神经受损。

2.3.2.4 特殊检查

尿垫试验:可以检测一定时间段内发生的尿失禁,并通过标准化状况下测量尿垫重量变化来量化尿失禁的量。尿垫试验的检测时间可以从不到 1 h 的短时间到 72 h 不等,短时的尿垫试验(1 h～2 h)通常在医师诊室内设计特定状态下(活动或运动)进行。如果患者膀胱容量恒定,不超过 1 h 的短期尿垫试验结果大多数是可靠的。国际尿失禁咨询会推荐的 1 h 尿垫试验方法是试验前 15 min 让患者喝水 500 mL,然后完成一系列的运动,1 h 尿垫试验把尿垫重量增加超过 1 g 定义为阳性。较长时间的 24 h 尿垫试验可以在家中进行,目的是使尿失禁的测定更接近现实生活,由于并未设定运动方式,24 h 尿垫试验对压力性和急迫性尿失禁都可以进行量化。

压力试验:患者咳嗽时,尿道外口有尿液流出,则表示压力试验为阳性,反之,则为阴性。压力性尿失禁患者表现为压力试验阳性,而急迫性尿失禁患者表现为压力试验阴性。但对于部分急迫性尿失禁患者,咳嗽等刺激可引起逼尿肌的收缩,从而出现尿道口尿液流出的延迟,这种现象仍定义为压力试验阴性。

棉签试验:将消毒润滑的棉签插入尿道,使棉签头处于尿道膀胱交界处,分别测量患者在静息时及 Valsalva 动作时,棉签与水平线之间的夹角。正常情况下,夹角应＜15°,提示解剖学支持正常,若夹角介于 15°～30°,表示结果不能确定,若夹角＞30°,提示解剖学支持薄弱,尿道活动度较大。单纯型压力

性尿失禁患者表现为棉签试验＞30°，而复杂型压力性尿失禁及急迫性尿失禁患者均可表现为棉签试验＜30°。

2.3.3 尿动力学检查

尿动力学检查是从流体力学角度观察尿失禁以确定尿失禁的类型，是目前诊断尿失禁最有效的方法，但必须在无泌尿系统感染的情况下进行，同时应注意无菌操作并防止发生逆行性感染。通过尿动力检查，对尿失禁进行分类、分型，从而采取针对性的治疗方法。

具有典型症状的单纯性压力性尿失禁不建议行尿动力学检查，避免过度检查，仅需用B超或导管测量残余尿，残余尿＜150 mL。而复杂型压力性尿失禁则应进行尿动力学检查，其表现为储尿期逼尿肌稳定，排尿期逼尿肌收缩有力，咳嗽时尿液流出，残余尿可≥150 mL。

通过尿动力学检查对压力性尿失禁进行分型（尤其对临床表现与查体不符者，意义更大）。根据腹部漏尿点压（Abdominal Leakage Point Pressure，ALPP）进行压力性尿失禁分型：① Ⅰ 型：ALPP≥90 cmH_2O；② Ⅱ 型：ALPP 60 cmH_2O～90 cmH_2O；③ Ⅲ 型：ALPP≤60 cmH_2O。其中，Ⅰ型和Ⅱ型为尿道高活动型压力性尿失禁，Ⅲ型为固有扩约肌障碍型压力性尿失禁。

根据最大尿道闭合压（Maximum Urethral Closure Pressure，MUCP）进行压力性尿失禁分型：①MUCP＞20 cmH_2O（或＞30 cmH_2O）提示尿道高活动型压力性尿失禁；②MUCP≤20 cmH_2O（或≤30 cmH_2O）提示固有扩约肌障碍型压力性尿失禁。

急迫性尿失禁患者尿动力检查结果表现为膀胱容量小，顺应性差，逼尿肌不稳定收缩，无膀胱残余尿。急迫性尿失禁的治疗与压力性尿失禁完全不同，因此准确区分二者是非常必要的。

混合性尿失禁的诊断应结合患者临床症状与尿动力学检查结果，不能仅因尿动力学结果的不明确而造成误诊或漏诊。混合性尿失禁患者尿动力学检查表现无特征，并非单纯的压力性尿失禁合并急迫性尿失禁的表现。

2.4 现代医学治疗

目前，现代医学治疗女性尿失禁的主要方法包括保守治疗和手术治疗两类。患者在接受尿失禁病情评估后，治疗方案应从保守治疗开始，保守治疗包括盆底肌功能训练（PFMT）、药物治疗、行为方式和生活习惯的改变等。保守治疗效果不佳的患者或重度尿失禁患者，可采取抗尿失禁手术，如填充剂尿道注射、耻骨后骶骨阴道悬吊术等。

PFMT 和尿失禁的药物治疗见 1.1.4 和 1.1.5。

3 指南制定过程

本指南的研制参考了 GRADE 方法学[9]与 WHO 指南研制手册[10]，研制过程主要包括形成临床问题和结局、构建证据体、制定推荐意见与方案 3 个关键环节。

3.1 临床问题的确定

利用 PICO 结构化临床关注调研问卷[11]，在国际范围内进行目标人群调研，共回收了 114 份来自医师的问卷。调研结果提示：最受关注的疾病类型依次是：压力性尿失禁、混合性尿失禁及急迫性尿失禁；最受关注的干预措施为毫针刺法、电针法及艾灸法；最受关注的结局为尿失禁次数、尿失禁生活质量相关量表、ICIQ-SF 评分。工作组依据目标人群的临床关注情况，初步拟定了临床问题和结局清单。通过两轮改良德尔菲法指南研制组（Guideline Development Group，GDG）专家共识，本指南纳入了 10 项临床问题，覆盖了最受关注的 PICO 要素。通过三轮改良德尔菲法 GDG 共识，本指南纳入了 11 类结局指标，按重要性排序依次为：24 h/72 h 尿失禁次数、尿失禁生活质量评分、用于评估急迫性尿失禁病情

的相关量表(U-IIQ、U-UDI)、国际尿失禁咨询委员会制定的用于评估尿失禁程度的相关问卷、患者满意度、尿垫使用数量、不良事件发生率、卫生经济学指标、24 h漏尿量、1 h尿垫试验漏尿量、用于评估泌尿系统问题的辅助检查。

临床问题及结局指标改良德尔菲共识[12]规则如下:

对于临床问题,重要性评级采用五分制李克特量表("非常重要"=5分,"重要"=4分,"一般重要"=3分,"不太重要"=2分,"不重要"=1分)。对于结局指标,采用GRADE重要性评级规则。据此,计算该题目的均值($\overline{X}$)、变异系数(CV=SD/$\overline{X}$)。

在完成第一轮德尔菲调研之后,召开本指南临床问题与结局的共识会议。GDG成员充分发表意见后,进行第二轮德尔菲投票。对于临床问题和结果,纳入本指南的条件为:重要性均值>3分且CV≤25%。当重要性均值<3且CV≤25%时,对应的临床问题或结局被排除;当CV>25%时,围绕该条目进行第二轮的会议讨论,在充分讨论后进行第三轮德尔菲调研。如在第三轮德尔菲调研中,相关条目的变异系数仍高于25%,则排除该临床问题或结局被排除。

3.2 证据体的检索、评价与综合

基于"常规毫针治疗女性UI""毫针深刺腰骶部腧穴治疗女性UI"和"艾灸治疗女性UI"分别开展系统检索,在4大英文数据库(PubMed、Embase、Cochrane、Web of Science)和4大中文数据库(中国知网、万方、维普、中国生物医学文献数据库)中,系统检索自建库起至2022年05月15日之间发表的文献。围绕关键词"女性尿失禁""针刺""艾灸"构建检索式。同时检索国际临床试验注册平台(https://trialsearch.who.int/Default.aspx)、美国临床试验注册平台(https://www.clinicaltrials.gov/)和中国临床试验注册中心(http://www.chictr.org.cn)中相关的试验。

分别依据10个临床问题的PICO要素特征制定纳入排除标准,进行文献特征提取、偏倚风险分析。围绕每个临床问题的不同结局进行Meta分析,并对证据体进行GRADE证据质量评价(偏倚风险、不一致性、不精确性、间接性和发表偏倚)。利用指南研发工具GDTpro[13]生成证据概要表(SoF)和证据决策表(EtD)。

围绕EtD框架中成本效益、健康公平性、可接受性和可行性等多维度考量,分别设计针对指南目标人群(使用者和适用人群)的针灸诊疗现状调研问卷。在国际范围内进行目标人群调研,共回收了299份有效问卷(包括来自中国医务人员的问卷232份,来自海外医务人员的问卷67份)。分别统计国内外医务人员的反馈情况,并提取汇总针灸治疗的卫生经济学、可接受性与可实施性证据。补充EtD框架中的相关证据。

3.3 推荐意见的形成

推荐意见由GDG成员充分掌握循证依据后,通过改良德尔菲法共识产生。首先,GDG成员充分阅读每个临床问题证据体(纳入文献特征表、偏倚风险评价表、SoF表和EtD框架)和共识规则后,围绕EtD框架的12个维度作出判断,并据此给出每个临床问题的推荐方向和强度。工作组对EtD框架和推荐意见的第一轮改良德尔菲调研结果进行统计。召开GDG共识会议,会上介绍证据体、共识规则及第一轮改良德尔菲投票的统计结果,并围绕每个问题的EtD框架,进行GDG成员讨论。经过充分讨论后,GDG成员再次对EtD框架和推荐意见进行投票。工作组依据第二轮改良德尔菲调研结果和GRADE网格共识规则,形成推荐意见。

GRADE网格共识规则[14]如下:

① 推荐或反对某一干预措施(和特定的对照措施相比较)至少需要50%的参与者认可,且少于20%选择对照措施;未满足此标准,则产生"可以推荐干预或对照";

② 一个推荐意见被列为强推荐而非条件性推荐,则需要得到至少70%的参与者强推荐。

推荐方案由GDG中的针灸专家对证据体中有效方案进行评价后,通过改良德尔菲法共识产生。

工作组分别围绕“常规毫针治疗”“毫针深刺腰骶部腧穴治疗”“艾灸治疗”,汇总证据体中关键结局(如尿失禁次数、ICIQ-SF 评分等)为阳性结果的 RCT 研究。提取每篇纳入研究的人群特征、干预措施细节,形成各个具体的针灸方案,进而归纳为多个毫针与艾灸治疗方案。在 GDG 的针灸专家中开展推荐方案的第一轮改良德尔菲调研,统计不同治疗方案的重要性评分和变异系数。召开 GDG 针灸专家共识会议,会上围绕每个推荐方案进行充分讨论,并进行第二轮改良德尔菲调研。工作组宣布调研结果,最终达成针灸专家共识,确定纳入的具体推荐方案。

推荐方案的改良德尔菲共识规则如下:

重要性评级采用五分制李克特量表(“非常推荐”=5 分,“比较推荐”=4 分,“一般推荐”=3 分,“不太推荐”=2 分,“不推荐”=1 分)。据此,计算每项推荐方案的均值($\overline{X}$)、变异系数($CV=SD/\overline{X}$)。

在完成第一轮德尔菲调研之后,召开本指南针灸推荐方案的 GDG 针灸专家共识会议。GDG 成员充分发表意见后,进行第二轮德尔菲投票。对于针灸推荐方案的德尔菲调研结果,纳入本指南的条件为:重要性均值≥3 分且 CV≤30%。当重要性均值<3 且 CV≤30%时,对应的推荐方案被排除;当 CV>30%时,围绕该条目进行会议讨论,在充分讨论后进行第二轮德尔菲调研。若在经过第三轮德尔菲调研后,相关推荐方案的变异系数仍高于 30%,则排除该推荐方案。

4 推荐意见

临床问题 1:相比于不做干预或安慰针,常规毫针治疗是否可以使女性尿失禁患者获益?
(1) 推荐意见
对于女性 UI 患者,可以推荐采用常规毫针治疗,而非不治疗或安慰针刺。(条件性推荐,基于低质量证据)
(2) 证据概述
本临床问题共纳入 2 项 RCT 研究,涉及 4 项结局。其中 24 h 尿失禁次数(关键结局)为极低质量证据;不良事件发生率(重要结局)、尿动力学检查-膀胱最大测压容积(重要结局)、尿动力学检查-膀胱充盈初感觉(重要结局)为低质量证据。 相比于不做治疗或安慰针,常规毫针治疗女性 UI 展示出中等程度的有利效果和微小的不利效果。相比于不治疗及安慰针,常规毫针治疗女性 UI 可能具有较好的成本效益,可能增加健康公平性。此外,常规毫针治疗易被患者和医生接受,且具有良好的可行性。 基于此,GDG 认为:相比于空白对照或安慰针,可以推荐常规毫针治疗女性 UI。
(3) 推荐说明
● **亚组考虑** 制定该推荐意见的证据体的患者群体涉及成年女性 UUI 和 MUI,故此该推荐意见适用于成年女性 MUI 和 UUI,对于成年女性 SUI 亦可参考本推荐意见。 对于以下女性 UI 患者群体推荐使用常规毫针治疗: ① 尿失禁症状严重影响生活质量的女性 UI 患者; ② 不抵触常规毫针治疗的女性 UI 患者。 ● **实施考虑** 实施该推荐意见前,建议患者在泌尿科专科就诊,明确诊断、病情及治疗方案。 实施该推荐意见时,应当充分参考本指南的实施注意事项。

（续）

● **监察与评估** 监察该指南发布后，是否有更多的女性 UI 患者接受常规毫针治疗而非不治疗。 评价实施该推荐意见后，女性 UI 患者在疗效指标（尿失禁次数、生活质量评分、尿失禁程度评分等）、安全性指标（不良事件发生率等）、卫生经济学指标（增量成本效益比、增量成本效果、增量成本效用等）及治疗满意度等方面的变化。 ● **科研的优先考虑** 开展常规毫针与安慰针刺/不治疗对照治疗女性 UI（尤其是 SUI）的高质量 RCT，进行常规毫针治疗的疗效和安全性评价。 开展常规毫针治疗特殊类型女性 UI（老年女性 UI、未成年女性 UI 等）的疗效和安全性评价。 开展常规毫针治疗女性 UI 对于疾病经济负担的研究和卫生经济学评价。 进一步优化常规毫针治疗方案，比较不同类型治疗方案对女性 UI 患者的疗效、安全性、成本效益及患者偏好的效力差异。
（4）推荐意见使用说明
常规毫针治疗可用于不同类型、不同程度的成年女性 UI 患者。 在以下情况，可考虑推荐常规毫针治疗： ① 尿失禁症状严重影响生活质量的女性 UI 患者； ② 不抵触常规毫针治疗的女性 UI 患者。
（5）治疗方案
● **取穴** 腹部：中极、关元、气海、大赫。 腰骶部：肾俞、膀胱俞、命门。 下肢部：三阴交、太溪、委中、复溜。 根据病情，酌情选用以上腧穴，建议采用腹部腧穴结合下肢部腧穴、腰骶部腧穴结合下肢部腧穴，或腹部、腰骶部腧穴结合下肢部腧穴的方案，进行治疗。 ● **操作方法** 针刺方法：毫针刺，中极、关元、气海、大赫，向耻骨联合方向斜刺 30 mm～40 mm；肾俞、膀胱俞、命门，直刺 20 mm～30 mm；余穴常规针刺深度；针刺中极、关元、气海、大赫时，使针感传至会阴部、尿道部为佳；余穴有酸麻胀重等得气针感。 补泻手法：依据“实则泻之，虚则补之”的原则实施补泻手法。 留针时间：20 min～30 min，可依据患者病情及可接受度等因素，酌情确定治疗时间。 ● **治疗频率** 至少 1 次/周，建议 2 次/周～3 次/周，依据患者的病情、可接受度等因素酌情而定。 ● **疗程** 至少 4 周为 1 个疗程，建议 2 个～3 个疗程，可依据患者的病情、可接受度等因素酌情而定。 ● **其他注意事项** 可依据患者的中医辨证分型，酌情增加配穴。 可依据患者的病情及可接受度，酌情配合毫针深刺次髎、中髎、会阳、胞肓、秩边等腰骶部腧穴。

临床问题 2:相比于盆底肌功能训练或口服药物,常规毫针治疗是否可以使女性尿失禁患者有同等或更多获益?
(1) 推荐意见
对于女性 UI 患者,相比于盆底肌功能训练或口服药物,可以推荐常规毫针治疗。(条件性推荐,基于极低质量证据)
(2) 证据概述
本临床问题共纳入 5 项 RCT 研究。 常规毫针治疗与盆底肌功能训练对照的 3 项 RCT,涉及 7 项结局,其中不良事件发生率(重要结局)、尿动力学检查-逼尿肌压力(重要结局)为低质量证据;ICIQ-SF 评分(关键结局)、24 h 漏尿量(重要结局)、尿动力学检查-最大尿流率、平均尿流率、最大尿道闭合压(重要结局)为极低质量证据。 常规毫针治疗与口服盐酸托特罗定对照的 1 项 RCT,涉及 2 项结局,其中不良事件发生率(重要结局)为低质量证据;24 h 尿失禁次数(关键结局)为极低质量证据。 常规毫针治疗与盆底肌功能训练+口服酒石酸托特罗定对照的 1 项 RCT,涉及 3 项结局,其中 1 h 尿垫试验漏尿量(重要结局)、不良事件发生率(重要结局)为低质量证据,ICIQ-SF 评分(关键结局)为极低质量证据。 相比于盆底肌功能训练或口服药物,常规毫针治疗女性 UI 展示出小效应的有利效果和微小的不利效果。相比于盆底肌功能训练或口服药物,常规毫针治疗女性 UI 可能具有较好的成本效益,可能增加健康公平性。此外,常规毫针治疗易被患者和医生接受,且具有良好的可行性。相关证据可信度极低。 基于此,GDG 认为:相比于盆底肌功能训练或口服药物,可以推荐常规毫针治疗女性 UI。
(3) 推荐说明
● **亚组考虑** 制定该推荐意见的证据体的患者群体涉及成年女性 SUI、UUI、MUI 患者,故此该推荐意见适用于成年女性 SUI、MUI、UUI。对于以下女性 UI 患者群体推荐使用常规毫针治疗: ① 不抵触常规毫针治疗的女性 UI 患者; ② 特别适用于盆底肌功能训练疗效欠佳的女性 UI 患者; ③ 特别适用于口服药物疗效欠佳的女性 UI 患者; ④ 担心药物副作用的女性 UI 患者。 ● **实施考虑** 实施该推荐意见前,建议患者在泌尿科专科就诊,明确诊断、病情及治疗方案。 实施该推荐意见前,建议评估现代医学治疗方案的必要程度及停用相关治疗方案的可能性。 实施该推荐意见时,应当充分参考本指南的实施注意事项。 ● **监察与评估** 监察该指南发布后,是否有更多的女性 UI 患者接受常规毫针治疗,而非盆底肌功能训练或口服药物治疗。 评价实施该推荐意见后,女性 UI 患者在疗效指标(尿失禁次数、生活质量评分、尿失禁程度评分等)、安全性指标(不良事件发生率等)、卫生经济学指标(增量成本效益比、增量成本效果、增量成本效用等)及治疗满意度等方面的变化。 ● **科研的优先考虑** 开展常规毫针治疗与现代医学疗法对照治疗女性 UI 的高质量 RCT,进行有效性及非劣效性探索,进行对于疾病经济负担的研究和卫生经济学评价。

（续）

（4）推荐意见使用说明
在以下情况，可考虑推荐常规毫针治疗： ① 不抵触常规毫针治疗的女性 UI 患者； ② 特别适用于盆底肌功能训练疗效欠佳的女性 UI 患者； ③ 特别适用于口服药物疗效欠佳的女性 UI 患者； ④ 担心药物副作用的女性 UI 患者。
（5）治疗方案
具体针刺方法为常规毫针治疗，详见第 1 项临床问题的推荐方案。

临床问题 3：在盆底肌功能训练或口服药物的基础上，加用常规毫针治疗是否可以使中重度女性尿失禁患者有更多获益？
（1）推荐意见
对于中重度女性 UI 患者，可以推荐在盆底肌功能训练或口服药物的基础上联合常规毫针治疗。（条件性推荐，基于低质量证据）
（2）证据概述
本临床问题共纳入 5 项常规毫针治疗联合盆底肌功能训练与单纯盆底肌功能训练对照的 RCT 研究，涉及 5 项结局，其中 ICIQ-SF 评分（关键结局）、IQoL 评分（关键结局）为低质量证据，24 h 尿失禁次数（关键结局）、1 h 尿垫试验漏尿量（重要结局）、尿动力学检查-盆底肌肉电位（重要结局）为极低质量证据。 未检索到常规毫针治疗联合口服药物治疗与单纯口服药物治疗对照的 RCT 研究。 相比于单纯盆底肌功能训练，联合应用常规毫针治疗中重度女性 UI 展示出中等程度的有利效果和微小的不利效果。相比于单纯盆底肌功能训练或口服药物治疗，联合应用常规毫针治疗中重度女性 UI 可能具有较好的成本效益，较容易被患者和医生接受，具有良好的可行性，并可能增加健康公平性。相关证据的可信度较低。 基于此，GDG 认为：对于中重度女性 UI 患者，可以推荐在盆底肌功能训练或口服药物的基础上联合常规毫针治疗。
（3）推荐说明
● **亚组考虑** 制定该推荐意见的证据体的患者群体涉及中重度成年女性 SUI 患者，故此该推荐意见适用于中重度成年女性 SUI，对于中重度成年女性 UUI 及 MUI 亦可参考本推荐意见。对于以下中重度女性 UI 患者群体推荐在盆底肌功能训练或口服药物的基础上联合常规毫针治疗： ① 不抵触常规毫针治疗的中重度女性 UI 患者； ② 特别适用于盆底肌功能训练疗效欠佳的女性 UI 患者； ③ 特别适用于口服药物疗效欠佳的女性 UI 患者。 对于经泌尿科医师评估病情，需进行手术治疗的女性 UI 患者，当遵从专科医师的治疗建议，谨慎使用针灸治疗。

（续）

● **实施考虑** 实施该推荐意见前，建议患者于泌尿科专科就诊，明确诊断、病情，中重度女性 UI 患者的治疗方案，应当遵从泌尿科医师的医嘱。 可依据患者的病情及接受度，酌情增加常规毫针治疗的治疗频率或延长疗程。 实施该推荐意见时，应当充分参考本指南的实施注意事项。 ● **监察与评估** 监察该指南发布后，是否有更多的中重度女性 UI 患者选择了在盆底肌功能训练或口服药物的基础上联合常规毫针治疗。 评价实施该推荐意见后，中重度女性 UI 患者在疗效指标（尿失禁次数、生活质量评分、尿失禁程度评分等）、安全性指标（不良事件发生率等）、卫生经济学指标（增量成本效益比、增量成本效果、增量成本效用等）及治疗满意度等方面的变化。 ● **科研的优先考虑** 开展在盆底肌功能训练或口服药物的基础上联合常规毫针治疗中重度女性 UI（尤其是 UUI、MUI）的疗效评价和安全性评价。 开展在盆底肌功能训练或口服药物的基础上联合常规毫针治疗中重度女性 UI 的卫生经济学评价以及对于疾病经济负担的研究。
（4）推荐意见使用说明
在以下情况，可考虑推荐在盆底肌功能训练或口服药物的基础上联合常规毫针治疗： ① 不抵触常规毫针治疗的中重度女性 UI 患者； ② 特别适用于盆底肌功能训练疗效欠佳的中重度女性 UI 患者； ③ 特别适用于口服药物疗效欠佳的中重度女性 UI 患者。 对于经泌尿科医师评估病情，需进行手术治疗的女性 UI 患者，当遵从专科医师的治疗建议，其他使用禁忌，参考指南实施注意事项。
（5）治疗方案
具体针刺方法为常规毫针治疗，详见第 1 项临床问题的推荐方案。 对于中重度女性 UI 患者，可依据患者的病情及接受度，酌情增加治疗频率或延长疗程。

临床问题 4：相比于不做干预或安慰针刺，毫针深刺腰骶部腧穴治疗是否可以使女性尿失禁患者获益？
（1）推荐意见
对于女性 UI 患者，可以推荐毫针深刺腰骶部腧穴治疗（DPSLAT），而非不治疗或安慰针刺。（条件性推荐，基于中等质量证据）
（2）证据概述
本临床问题共纳入 6 项 RCT 研究，涉及 12 项结局。其中尿失禁次数（3 个月～6 个月随访）（关键结局）、ICIQ-SF 评分（治疗后）（关键结局）、1 h 尿垫试验漏尿量（重要结局）及不良事件发生率（重要结局）为中等质量证据；尿失禁次数（治疗后）（关键结局）、尿失禁次数（3 个月以内随访）（关键结局）、I-QoL 评分（治疗后）（关键结局）、I-QoL 评分（3 个月以内随访）（关键结局）、ICIQ-SF 评分（3 个月以内随访）（关键结局）、ICIQ-SF 评分（3 个月～6 个月随访）（关键结局）、1 h 尿垫试验漏尿量（3 个月以内随访）（重要结局）、72 h 尿垫使用数量（重要结局）为低质量证据。

（续）

相比于不做治疗或安慰针，DPSLAT 治疗女性 UI 展示出中等程度的有利效果和微小的不利效果。相比于不治疗或安慰针，DPSLAT 治疗女性 UI 可能具有较好的成本效益，可能增加健康公平性。此外，DPSLAT 易被患者和医生接受，且具有良好的可行性。相关证据呈现中等可信度。 基于此，GDG 认为：相比于空白对照或安慰针，可以推荐 DPSLAT 治疗女性 UI。
（3）推荐说明
● **亚组考虑** 制定该推荐意见的证据体的患者群体涉及成年女性 SUI 和 MUI，故此该推荐意见适用于成年女性 SUI 和 MUI，对于成年女性 UUI 亦可参考本推荐意见。 对于以下女性 UI 患者群体推荐使用 DPSLAT： ① 尿失禁症状影响日常生活的女性 UI 患者； ② 不抵触 DPSLAT 的女性 UI 患者。 ● **实施考虑** 实施该推荐意见前，建议患者在泌尿科专科就诊，明确诊断、病情及治疗方案。 实施该推荐意见时，应当充分参考本指南的实施注意事项。 ● **监察与评估** 监察该指南发布后，是否有更多的女性 UI 患者接受 DPSLAT，而非不治疗。 评价实施该推荐意见后，女性 UI 患者在疗效指标（尿失禁次数、生活质量评分、尿失禁程度评分等）、安全性指标（不良事件发生率等）、卫生经济学指标（增量成本效益比、增量成本效果、增量成本效用等）及治疗满意度等方面的变化。 ● **科研的优先考虑** 开展 DPSLAT 与安慰针刺对照治疗女性 UUI 的高质量 RCT，进行 DPSLAT 的疗效和安全性评价。 开展 DPSLAT 治疗特殊类型女性 UI（老年女性 UI、未成年女性 UI 等）的疗效和安全性评价。 开展 DPSLAT 治疗女性 UI 的疾病经济负担的研究和卫生经济学评价。 比较不同类型 DPSLAT 治疗方案对女性 UI 患者的疗效、安全性、成本效益及患者偏好的效力差异。
（4）推荐意见使用说明
DPSLAT 可用于不同类型、不同程度的成年女性 UI 患者。 在以下情况，可考虑推荐 DPSLAT： ① 不抵触 DPSLAT 的女性 UI 患者； ② 尿失禁症状影响日常生活的女性 UI 患者。
（5）治疗方案
● **DPSLAT 方案一** ① 取穴 中髎、会阳。 ② 操作方法 体位：患者取俯卧位，充分暴露腰骶部。 针具：0.3 mm×75 mm 的一次性针灸针。

（续）

针刺法：中髎穴向内下 30°～45°角进行毫针斜刺，针刺深度在 50 mm～60 mm，会阳穴稍向外上行毫针斜刺，针刺深度在 50 mm～60 mm，行提插捻转手法，以获得局部酸麻胀重等得气感，横向连接电针仪电极于双侧中髎穴和会阳穴的针柄上，选用连续波，频率 50 Hz，电流 1 mA～5 mA。留针时间：30 min。

③ 治疗频率

3 次/周。

④ 疗程

轻度压力性、混合性尿失禁：6 周～8 周。

中度、重度压力性、混合性尿失禁：8 周～12 周。

⑤ 适用人群注意事项

本方案适用于成年女性 MUI 和 SUI 患者，对于成人女性 UUI 患者，亦可参考本推荐方案进行治疗。

因本方案可能造成较为强烈的针感，临床应用前应向患者充分说明，不能耐受强烈针感的患者应谨慎使用。

⑥ 操作方法注意事项

因本方案有一定的操作难度，指南使用者在临床应用前，应接受该疗法的相关培训，并熟悉相关解剖结构。

针具：依据女性 UI 患者的体型、耐受程度等因素，酌情选择规格（0.25～0.3）mm×（60～75）mm 的一次性针灸针.

针刺角度：依据不同人群、种族女性 UI 患者的生理结构差异，可酌情调整针刺角度，以刺入骶后孔为度。

电针应用：可依据患者的病情及可接受度，酌情选用电针及其治疗参数。

治疗频率：由于国际范围内针刺治疗的频率存在一定的差异，推荐本方案的治疗频率为：至少 1 次/周，建议 2 次/周～3 次/周，依据患者的病情、可接受度等因素酌情而定。

疗程：由于国际范围内针刺治疗的疗程存在一定的差异，推荐本方案的疗程为：至少 6 周，建议 6 周～12 周，依据患者的病情、可接受度等因素酌情而定。

- **DPSLAT 方案二**

① 取穴

秩边。

② 操作方法

体位：患者取俯卧位，充分暴露腰骶部。

针具：0.25 mm×125 mm 的一次性针灸针。

针刺法：从秩边穴进针，向下深刺约 110 mm 透向水道穴，进针时使针身同躯干矢状面呈 20°角，同时与躯干水平面平行，以针感（胀感、热感、舒快感）到达小腹、前阴、会阴为度。

留针时间：30 min。

③ 治疗频率

至少 1 次/周，建议 2 次/周～3 次/周，依据患者的病情、可接受度等因素酌情而定。

④ 疗程

至少 2 周，建议 2 周～4 周，依据患者的病情、可接受度等因素酌情而定。

（续）

⑤ 适用人群注意事项 该治疗方案适用于成年女性 SUI 患者，对于成年女性 UUI、MUI 患者，亦可参考本推荐方案进行治疗。 因本方案可能造成较为强烈的针感，临床应用前应向患者充分说明，不能耐受强烈针感的患者应谨慎使用。 ⑥ 操作方法注意事项 因本方案有一定的操作难度，指南使用者在临床应用前，应接受该疗法的相关培训，并熟悉相关解剖结构。 依据不同人群、种族女性的生理结构差异，可酌情调整针刺深度，以针感到达小腹、前阴、会阴为度。

临床问题 5：相比于盆底肌功能训练或口服药物，毫针深刺腰骶部腧穴治疗是否可以使女性尿失禁患者有同等或更多获益？
（1）推荐意见
对于女性 UI 患者，相比于盆底肌功能训练或口服药物，可以推荐 DPSLAT。（条件性推荐，基于低质量证据）
（2）证据概述
本临床问题共纳入 9 项 RCT 研究，DPSLAT 与盆底肌功能训练对照的 3 项 RCT，涉及 8 项结局，其中 1 h 尿垫试验漏尿量（治疗后、3 个月及以内随访、3 个月～6 个月随访）为低质量证据；尿失禁次数（治疗后）（关键结局）、ICIQ-SF 评分（治疗后、3 个月及以内随访、3 个月～6 个月随访）（重要结局）、不良事件发生率（重要结局）为极低质量证据。 DPSLAT 与盆底肌功能训练＋口服索利那新对照的 6 项 RCT，涉及 3 项结局，其中尿失禁次数（治疗后、3 个月及以内随访、3 个月～6 个月随访）（关键结局）、ICIQ-SF 评分（治疗后、3 个月及以内随访、3 个月～6 个月随访）（关键结局）、1 h 尿垫试验漏尿量（治疗后）（重要结局）、患者满意人数（治疗后）（重要结局）、不良事件发生率（重要结局）为低质量证据；生活质量 IIQ-7 评分（关键结局）、患者满意度评分（治疗后、3 个月～6 个月随访）、患者满意人数（3 个月～6 个月随访），为极低质量证据。 未检索到 DPSLAT 与单纯口服药物对照的 RCT 研究。 相比于盆底肌功能训练或盆底肌功能训练联合口服药物，DPSLAT 治疗女性 UI 展示出中等程度的有利效果和小的不利效果，相关证据的可信度较低。相比于盆底肌功能训练或口服药物，DPSLAT 治疗女性 UI 可能具有较好的成本效益，并可能增加健康公平性。此外，DPSLAT 比较容易被患者和医生接受，具有一定的可行性。证据体的可信度较低。 基于此，GDG 认为：相比于盆底肌功能训练或口服药物，可以推荐 DPSLAT 治疗女性 UI。
（3）推荐说明
● **亚组考虑** 该推荐意见的证据体的患者群体涉及成年女性 SUI、MUI 患者，故此该推荐意见适用于成年女性 SUI、MUI。对于成年女性 UUI 患者亦可参考本推荐意见。 对于以下女性 UI 患者群体推荐使用 DPSLAT： ① 不抵触 DPSLAT 的女性 UI 患者；

（续）

② 特别适用于盆底肌功能训练疗效欠佳的女性 UI 患者； ③ 特别适用于口服药物疗效欠佳的女性 UI 患者； ④ 担心药物副作用的女性 UI 患者。 ● **实施考虑** 实施该推荐意见前，建议患者在泌尿科专科就诊，明确诊断、病情及治疗方案。 实施该推荐意见前，建议评估现代医学治疗方案的必要程度及停用治疗方案的可能性。 实施该推荐意见时，应当充分参考本指南的实施注意事项。 ● **监察与评估** 监察该指南发布后，是否有更多的女性 UI 患者接受 DPSLAT，而非盆底肌功能训练或口服药物治疗。 评价实施该推荐意见后，女性 UI 患者在疗效指标(尿失禁次数、生活质量评分、尿失禁程度评分等)、安全性指标(不良事件发生率等)、卫生经济学指标(增量成本效益比、增量成本效果、增量成本效用等)及治疗满意度等方面的变化。 ● **科研的优先考虑** 开展 DPSLAT 与现代医学疗法对照治疗女性 UI 的高质量 RCT 研究，进行有效性及非劣效性探索，对于疾病经济负担的研究和卫生经济学评价。
(4) 推荐意见使用说明
在以下情况，可考虑推荐 DPSLAT： ① 不抵触 DPSLAT 的女性 UI 患者； ② 特别适用于盆底肌功能训练疗效欠佳的女性 UI 患者； ③ 特别适用于口服药物疗效欠佳的女性 UI 患者； ④ 担心药物副作用的女性 UI 患者。
(5) 治疗方案
具体治疗方案参考 DPSLAT 方案一、方案二，详见第 4 项临床问题的治疗方案。

临床问题 6：在盆底肌功能训练或口服药物的基础上，加用毫针深刺腰骶部腧穴治疗是否可以使中重度女性尿失禁患者有更多获益？
(1) 推荐意见
对于中重度女性 UI 患者，可以推荐在盆底肌功能训练或口服药物的基础上联合 DPSLAT。(条件性推荐，基于极低质量证据)
(2) 证据概述
本临床问题共纳入 3 项 DPSLAT 联合盆底肌功能训练与单纯盆底肌功能训练对照的 RCT 研究，涉及 4 项结局，其中生活质量 IIQ-7 评分(关键结局)、ICIQ-SF 评分(关键结局)、1 h 尿垫试验漏尿量(重要结局)、不良事件发生率(重要结局)均为极低质量证据。 未检索到 DPSLAT 联合口服药物治疗与单纯口服药物治疗对照的 RCT 研究。

（续）

相比于单纯盆底肌功能训练，联合应用 DPSLAT 治疗中重度女性 UI 展示出中等程度的有利效果和微小的不利效果。相比于单纯盆底肌功能训练或口服药物治疗，联合应用 DPSLAT 治疗中重度女性 UI 可能具有较好的成本效益，较容易被患者和医生接受，具有一定的可行性，并可能增加健康公平性。相关证据的可信度极低。 基于此，GDG 认为：对于中重度女性 UI 患者，可以推荐在盆底肌功能训练或口服药物的基础上联合 DPSLAT。
（3）推荐说明
● 亚组考虑 制定该推荐意见的证据体的患者群体涉及中重度成年女性 SUI 患者，故此该推荐意见适用于中重度成年女性 SUI，对于中重度成年女性 UUI 及 MUI 亦可参考本推荐意见。 对于以下女性 UI 患者群体推荐使用 DPSLAT： ① 不抵触 DPSLAT 的中重度女性 UI 患者； ② 特别适用于盆底肌功能训练疗效欠佳的女性 UI 患者； ③ 特别适用于口服药物疗效欠佳的女性 UI 患者。 对于经泌尿科医师评估病情，需进行手术治疗的女性 UI 患者，当遵从专科医师的治疗建议，谨慎使用针灸治疗。 ● 实施考虑 实施该推荐意见前，建议患者于泌尿科专科就诊，明确诊断、病情，中重度女性 UI 患者的治疗方案，应当遵从泌尿科医师的医嘱。 可依据患者的病情及接受度，酌情增加 DPSLAT 的频率或疗程。 实施该推荐意见时，应当充分参考本指南的实施注意事项。 ● 监察与评估 监察该指南发布后，是否有更多的中重度女性 UI 患者选择了在盆底肌功能训练或口服药物的基础上联合 DPSLAT。 评价实施该推荐意见后，中重度女性 UI 患者在疗效指标（尿失禁次数、生活质量评分、尿失禁程度评分等）、安全性指标（不良事件发生率等）、卫生经济学指标（增量成本效益比、增量成本效果、增量成本效用等）及治疗满意度等方面的变化。 ● 科研的优先考虑 开展在盆底肌功能训练或口服药物的基础上联合 DPSLAT 治疗中重度女性 UI（尤其是 UUI、MUI）的疗效评价、安全性评价以及对于疾病经济负担的研究和卫生经济学评价。
（4）推荐意见使用说明
在以下情况，可考虑推荐在盆底肌功能训练或口服药物的基础上联合 DPSLAT： ① 不抵触 DPSLAT 的中重度女性 UI 患者； ② 特别适用于盆底肌功能训练疗效欠佳的中重度女性 UI 患者； ③ 特别适用于口服药物疗效欠佳的中重度女性 UI 患者。 对于经泌尿科医师评估病情，需进行手术治疗的女性 UI 患者，当遵从专科医师的治疗建议，其他使用禁忌，参考本指南的指南实施注意事项。
（5）治疗方案
具体治疗方案参考 DPSLAT 方案一、方案二，详见第 4 项临床问题的治疗方案。 对于中重度女性 UI 患者，可依据患者的病情及接受度，酌情增加治疗频率或延长疗程。

临床问题7：相比于不做干预，艾灸治疗是否可以使女性尿失禁患者获益？
(1) 推荐意见
对于女性UI患者，可以推荐艾灸治疗，而非不治疗。(条件性推荐，基于极低质量证据)
(2) 证据概述
本临床问题共纳入4项艾灸治疗女性UI的病例系列研究以及9项艾灸治疗中风后尿失禁的RCT研究作为补充证据，涉及7项结局。其中24 h尿失禁次数(关键结局)、生活治疗IQoL评分(关键结局)、ICIQ-SF评分(关键结局)、1 h尿垫试验漏尿量(重要结局)、不良事件发生率(重要结局)均为极低质量证据。 相比于不做治疗，艾灸治疗女性UI展示出中等程度的有利效果和微小的不利效果。相比于不治疗，艾灸治疗女性UI可能具有较好的成本效益，可能增加健康公平性。此外，艾灸治疗比较容易被患者和医生接受，具有一定的可行性。相关证据的可信度极低。 基于此，GDG认为：相比于空白对照，可以推荐艾灸治疗女性UI。
(3) 推荐说明
● 亚组考虑 制定该推荐意见的证据体的患者群体涉及成年女性SUI患者，故此该推荐意见适用于成年女性SUI，对于成年女性UUI、MUI亦可参考本推荐意见。 对于以下女性UI患者群体推荐使用艾灸治疗： ① 不抵触艾灸治疗的女性UI患者； ② 尿失禁症状影响日常生活的女性UI患者； ③ 特别适用于产后尿失禁及老年女性UI患者； ④ 特别适用于中医辨证为“虚”证的女性UI患者。 ● 实施考虑 实施该推荐意见前，建议患者在泌尿科专科就诊，明确诊断、病情及治疗方案。 实施该推荐意见时，应当充分参考本指南的实施注意事项。 ● 监察与评估 监察该指南发布后，是否有更多的女性UI患者接受艾灸治疗而非不治疗。 评价实施该推荐意见后，女性UI患者在疗效指标(尿失禁次数、生活质量评分、尿失禁程度评分等)、安全性指标(不良事件发生率等)、卫生经济学指标(增量成本效益比、增量成本效果、增量成本效用等)及治疗满意度等方面的变化。 ● 科研的优先考虑 开展艾灸治疗与空白对照治疗女性UI的高质量RCT研究，验证艾灸治疗的疗效和安全性，开展艾灸治疗女性UI的疾病经济负担的研究和卫生经济学评价。 开展艾灸治疗特殊类型女性UI(老年女性UI、未成年女性UI等)的疗效和安全性评价。
(4) 推荐意见使用说明
艾灸治疗可用于不同类型、不同程度的成年女性UI患者。 在以下情况，可考虑推荐艾灸治疗： ① 不抵触艾灸治疗的女性UI患者； ② 尿失禁症状影响日常生活的女性UI患者； ③ 特别适用于产后尿失禁及老年女性UI患者； ④ 特别适用于中医辨证为“虚”证的女性UI患者。

（续）

（5）治疗方案
● **艾灸治疗方案一：悬起灸治疗** ① 取穴 关元、中极、气海、肾俞、次髎，依据患者病情，酌情选穴。 ② 操作方法 采用悬起灸法进行治疗，使患者腧穴局部有温热感而无灼痛感为宜，依据患者的病情及耐受度，酌情确定治疗时间。 在临床治疗中，必要时可配合应用温灸器灸，对腹部、腰骶部区域内的腧穴同时进行治疗，以缩短治疗时长，节省人力资源。 ● **艾灸治疗方案二：温针灸治疗** ① 取穴 中极、气海、关元、肾俞、次髎、足三里，依据患者病情，酌情选穴。 ② 操作方法 采用温针灸法进行治疗。依据患者的病情及耐受度酌情确定治疗时间。 ● **艾灸治疗方案三：隔物灸治疗** ① 取穴 中极、关元、气海、神阙、肾俞、膀胱俞、关元俞，依据患者病情，酌情选穴。 ② 间隔药物 生姜片：制作直径为 2 cm～3 cm、厚为 0.2 cm～0.3 cm 的生姜片，中间针刺数孔。 药饼：选用具有温阳作用的一种或多种中药（如附子、肉桂、桂枝等）研磨成末，以生姜汁调和为药泥。 ③ 操作方法 采用隔物灸法进行治疗。依据患者的病情及耐受度酌情确定治疗时间。 ● **艾灸治疗方案四：热敏灸治疗** ① 取穴 在气海、中极、关元、肾俞、膀胱俞、次髎、三阴交、百会等穴周寻找热敏点。 ② 操作方法 采用热敏灸法进行治疗。依据患者的病情及耐受度酌情确定治疗时间。 ● **艾灸治疗的频率** 至少 1 次/周，建议 2 次/周～3 次/周，依据患者的病情、可接受度等因素酌情而定。 ● **艾灸治疗的疗程** 4 周为一个疗程，建议 1 个～2 个疗程，依据患者的病情、可接受度等因素酌情而定。 ● **艾灸治疗的其他注意事项** ① 对艾灸治疗灸材过敏者，禁用艾灸治疗； ② 不能耐受施灸时所产生的烟雾者，不宜使用艾灸治疗； ③ 温针灸治疗、隔物灸治疗、热敏灸治疗具有一定的操作要求，施术人员应接受相关培训。

临床问题 8:相比于盆底肌功能训练或口服药物,艾灸治疗是否可以使女性尿失禁患者有同等或更多获益?
(1) 推荐意见
对于女性 UI 患者,可以推荐艾灸治疗或盆底肌功能训练或口服药物治疗。(条件性推荐干预或对照,基于极低质量证据)
(2) 证据概述 本临床问题共纳入 1 项艾灸治疗与盆底肌功能训练对照的 RCT 研究,涉及 3 项结局。其中 ICIQ-SF 评分(治疗后)(关键结局)、ICIQ-SF 评分(3 个月～6 个月随访)(关键结局)、不良事件发生率(重要结局),均为极低质量证据。 未检索到艾灸治疗与口服药物治疗对照的 RCT 研究。 相比于盆底肌功能训练,艾灸治疗女性 UI 展示出微小的有利效果和微小的不利效果。相比于盆底肌功能训练或口服药物,艾灸治疗女性 UI 可能具有同等的成本效益,可能增加健康公平性。此外,艾灸治疗比较容易被患者和医生接受,具有一定的可行性。相关证据的可信度极低。 基于此,GDG 认为:对于女性 UI 患者,可以推荐艾灸治疗或盆底肌功能训练或口服药物治疗。
(3) 推荐说明
● **亚组考虑** 该推荐意见的证据体的患者群体涉及成年女性 SUI 患者,故此该推荐意见适用于成年女性 SUI。对于成年女性 UUI、MUI 患者亦可参考本推荐意见。 在遵从泌尿科专科医师的诊断及治疗方案的前提下,对于以下女性 UI 患者群体推荐使用艾灸治疗: ① 希望获得艾灸治疗的女性 UI 患者; ② 产后尿失禁及老年女性 UI 患者; ③ 中医辨证为“虚”证的女性 UI 患者。 ● **实施考虑** 实施该推荐意见前,建议患者在泌尿科专科就诊,明确诊断、病情及治疗方案。 实施该推荐意见前,建议评估现代医学治疗方案的必要程度及停用治疗方案的可能性。 实施该推荐意见时,应当充分参考本指南的实施注意事项。 ● **监察与评估** 监察该指南发布后,是否有更多的女性 UI 患者接受艾灸治疗。 评价实施该推荐意见后,女性 UI 患者在疗效指标(尿失禁次数、生活质量评分、尿失禁程度评分等)、安全性指标(不良事件发生率等)、卫生经济学指标(增量成本效益比、增量成本效果、增量成本效用等)及治疗满意度等方面的变化。 ● **科研的优先考虑** 开展艾灸治疗与现代医学疗法对照治疗女性 UI 的高质量 RCT,进行有效性及非劣效性探索,进行疾病经济负担的研究和卫生经济学评价及患者偏好评价。
(4) 推荐意见使用说明
在以下情况,可以推荐艾灸治疗: ① 希望获得艾灸治疗的女性 UI 患者; ② 产后 UI 及老年女性 UI 患者;

（续）

③ 中医辨证为“虚”证的女性 UI 患者。 在以下情况，可以推荐盆底肌功能训练：泌尿科医师评估病情后，建议首先接受盆底肌功能训练的女性 UI 患者。 在以下情况，可以推荐口服药物治疗：泌尿科医师评估病情后，建议首先接受口服药物治疗的女性 UI 患者。
（5）治疗方案
具体治疗方案参考悬起灸治疗、温针灸治疗、隔物灸治疗及热敏灸治疗，详见第 7 项临床问题的治疗方案。

临床问题 9：在盆底肌功能训练或口服药物的基础上，加用艾灸治疗是否可以使中重度女性尿失禁患者有更多获益？
（1）推荐意见
对于中重度女性 UI 患者，可以推荐在盆底肌功能训练或口服药物的基础上联合艾灸治疗。（条件性推荐，基于极低质量证据）
（2）证据概述
本临床问题共纳入 18 项 RCT 研究。艾灸治疗联合盆底肌功能训练与单纯盆底肌功能训练对照的 17 项 RCT 研究，涉及 10 项结局，其中尿失禁次数（治疗后、3 个月及以内随访）（关键结局）、生活质量评分（IQoL、GQOLI-74）（关键结局）、ICIQ-SF 评分（治疗后、3 个月及以内随访）（关键结局）、24 h 漏尿量（治疗后、3 个月及以内随访）（重要结局）、1 h 尿垫试验漏尿量（治疗后、3 个月及以内随访）（重要结局）、尿动力学检查-平均尿流率（重要结局）、不良事件发生率（重要结局）均为极低质量证据。 艾灸治疗联合口服药物与单纯口服药物对照的 1 项 RCT 研究，涉及 3 项结局，其中尿失禁次数（治疗后）（关键结局）、尿动力学检查-最大尿流率、平均尿流率（重要结局）均为极低质量证据。 相比于单纯盆底肌功能训练或口服药物治疗，联合应用艾灸治疗中重度女性 UI 展示出中等程度的有利效果和微小的不利效果。相比于单纯盆底肌功能训练或口服药物治疗，联合应用艾灸治疗中重度女性 UI 可能具有较好的成本效益，较容易被患者和医生接受，具有一定的可行性，并可能增加了健康公平性。相关证据的可信度极低。 基于此，GDG 认为：相比于单纯盆底肌功能训练或口服药物治疗，可以推荐在盆底肌功能训练或口服药物的基础上联合艾灸治疗中重度女性 UI。
（3）推荐说明
• **亚组考虑** 制定该推荐意见依据的证据体，所涉及的患者群体为成年女性中重度 SUI，故此该推荐意见适用于成年女性中重度 SUI 患者，对于成年女性中重度 UUI、MUI 患者亦可参考本推荐意见。 对于以下女性 UI 患者群体推荐使用艾灸治疗： ① 不抵触艾灸治疗的中重度女性 UI 患者； ② 特别适用于盆底肌功能训练效果欠佳的女性 UI 患者； ③ 特别适用于口服药物效果欠佳的女性 UI 患者。 对于经泌尿科医师评估病情，需进行手术治疗的女性 UI 患者，当遵从专科医师的治疗建议，其他使用禁忌参考指南实施注意事项。

（续）

● **实施考虑** 实施该推荐意见前，建议患者于泌尿科专科就诊，明确诊断、病情，中重度女性 UI 患者的治疗方案，应当遵从泌尿科医师的医嘱。 可依据患者的病情及接受度，酌情增加艾灸治疗的频率或疗程。 实施该推荐意见时，应当充分参考本指南的实施注意事项。 ● **监察与评估** 监察该指南发布后，是否有更多的中重度女性 UI 患者选择了在盆底肌功能训练或口服药物的基础上联合艾灸治疗。 评价实施该推荐意见后，中重度女性 UI 患者在疗效指标（尿失禁次数、生活质量评分、尿失禁程度评分等）、安全性指标（不良事件发生率等）、卫生经济学指标（增量成本效益比、增量成本效果、增量成本效用等）及治疗满意度等方面的变化。 ● **科研的优先考虑** 开展在盆底肌功能训练或口服药物的基础上联合艾灸治疗中重度女性 UI（尤其是 UUI、MUI）的疗效评价、安全性评价，疾病经济负担的研究和卫生经济学评价。
（4）推荐意见使用说明 在以下情况，可考虑推荐在盆底肌功能训练或口服药物的基础上联合艾灸治疗： ① 不抵触艾灸治疗的中重度女性 UI 患者； ② 特别适用于盆底肌功能训练疗效欠佳的中重度女性 UI 患者； ③ 特别适用于口服药物疗效欠佳的中重度女性 UI 患者。 对于经泌尿科医师评估病情，需进行手术治疗的女性 UI 患者，当遵从专科医师的治疗建议，其他使用禁忌参考指南实施注意事项。
（5）治疗方案
具体治疗方案参考悬起灸治疗、温针灸治疗、隔物灸治疗及热敏灸治疗，详见第 7 项临床问题的治疗方案。 对于中重度女性 UI 患者，可依据患者的病情及接受度，酌情增加艾灸治疗频率或延长疗程。

临床问题 10：相比于单纯毫针治疗或艾灸治疗，两种治疗的联合应用是否可以使女性尿失禁患者有更多获益？
（1）推荐意见
对于女性 UI 患者，可以推荐毫针联合艾灸治疗。（条件性推荐，基于极低质量证据）
（2）证据概述
本临床问题共纳入 6 项 RCT 研究，涉及 7 项结局。尿失禁次数（关键结局）、尿动力学检查-残余尿超声膀胱残余尿量（重要结局）为低质量证据，ICIQ-SF 评分（关键结局）、1 h 尿垫试验漏尿量（重要结局）为极低质量证据。 相比于单纯毫针或艾灸治疗，毫针联合艾灸治疗展示出中等程度的有利效果和微小的不利效果。相比于单纯毫针或艾灸治疗，毫针联合艾灸治疗女性 UI 可能具有较好的成本效益，可能增加健康公平性。此外，毫针联合艾灸治疗易被患者和医生接受，且具有良好的可行性。相关证据可信度较低。 基于此，GDG 认为：相比于单纯毫针或艾灸治疗，可以推荐毫针联合艾灸治疗女性 UI。

（续）

（3）推荐说明
● 亚组考虑 制定该推荐意见依据的证据体，所涉及的患者群体为成年女性 SUI、MUI 患者，故此该推荐意见适用于成年女性 MUI、SUI 患者，对于成年女性中重度 UUI 患者亦可参考本推荐意见。 对于单纯毫针或艾灸治疗效果欠佳的女性 UI 患者，可考虑推荐毫针联合艾灸治疗。 ● 实施考虑 实施该推荐意见前，建议患者在泌尿科专科就诊，明确诊断、病情及治疗方案。 实施该推荐意见前，建议评估现代医学治疗方案的必要程度及停用治疗方案的可能性。 实施该推荐意见时，应当充分参考本指南的实施注意事项。 ● 监察与评估 监察该指南发布后，是否有更多的女性 UI 患者接受毫针联合艾灸治疗。 评价实施该推荐意见后，女性 UI 患者在疗效指标（尿失禁次数、生活质量评分、尿失禁程度评分等）、安全性指标（不良事件发生率等）、卫生经济学指标（增量成本效益比、增量成本效果、增量成本效用等）及治疗满意度等方面的变化。 ● 科研的优先考虑 开展毫针联合艾灸治疗女性 UI 的高质量 RCT，进行有效性及非劣效性探索，进行疾病经济负担的研究和卫生经济学评价及患者偏好评价。
（4）推荐意见使用说明
对于单纯毫针治疗或艾灸治疗疗效欠佳的女性 UI 患者，可考虑推荐毫针联合艾灸治疗。
（5）治疗方案
具体毫针治疗方案参考常规毫针治疗、DPSLAT 方案一、DPSLAT 方案二，详见第 1 项、第 4 项临床问题的治疗方案。 具体艾灸治疗方案参考悬起灸治疗、温针灸治疗、隔物灸治疗及热敏灸治疗，详见第 7 项临床问题的治疗方案。

5 获取途径

本指南在世界针灸学会联合会网站发布，纸质版由中国标准出版社出版。此外，指南的核心内容将于英文期刊发布。用户可通过上述途径获取本指南。

6 未来可开展的研究

未来可开展的研究见“推荐意见”中“科研的优先考虑”。

7 局限和不足

本指南基于目标用户的临床需求调研，围绕最受关注的干预措施（毫针刺法和艾灸）进行了临床问题和推荐意见的研制。对于其他治疗女性尿失禁的有效针灸方法（穴位贴敷、耳穴压丸等）并未形成临

床问题和推荐意见。

8 实施注意事项

8.1 法律法规注意事项

指南使用者需要在遵守所在国家/地区法律法规的前提下，采用针灸疗法治疗女性尿失禁。

8.2 医疗机构注意事项

8.2.1 医疗机构需具备针灸疗法的准入资格。

8.2.2 医疗机构需具备可以应对针灸相关不良事件的抢救设施及药物。

8.2.3 对于艾灸治疗，建议医疗机构设立专门的灸疗室，配备排风机和防火设施。

8.3 医师注意事项

8.3.1 医师需要具备针灸医师资质或合法的针灸执业资格。

8.3.2 医师在进行针灸治疗前，应向患者充分说明相关针灸治疗方案的可能获益及潜在风险，在征得患者的同意后，再进行治疗。

8.3.3 医师在进行针灸治疗时，需预防不良事件的发生（如晕针、创伤性气胸、刺伤脏器、烫伤等），并具备处理针灸相关不良事件的能力。

8.4 需向患者明确的注意事项

以下情况，要特别注意禁用或慎用针灸治疗。

8.4.1 对于空腹、过饱、极度疲劳和对针灸疗法恐惧的患者，不宜进行针灸治疗，对于身体瘦弱的患者，针灸操作手法不宜过强。

8.4.2 对于孕妇，不宜刺激腹部及腰骶部腧穴，不宜刺激具有较强通经活血作用的腧穴（如合谷、三阴交等）。

8.4.3 对于有出血倾向的患者，慎重使用针灸治疗。

8.4.4 对于穴位处皮肤有感染、溃疡或肿瘤者，慎重使用针灸治疗。

8.4.5 施灸过程应注意在通风环境中进行，并防止燃烧的艾绒脱落烧伤皮肤和衣物。

附 录 A
指南工作组成员

A.1 指南研制组 GDG 成员（排名不分先后）

姓名	国家	专业	角色/身份	机构
陈业孟	美国	针灸学	针灸专家	纽约中医学院
邓汉文	澳大利亚	针灸学	针灸专家	悉尼中医学院
王晓明	日本	针灸学	针灸专家	京东平城大学
董红光	瑞士	针灸学	针灸专家	日内瓦大学
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戴昭宇	中国	针灸学	针灸专家	香港浸会大学
贾春生	中国	针灸学	针灸专家	河北中医学院
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杨女士	中国	—	女性尿失禁患者代表	—

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附 录 B
缩略语表

全称	缩写
腹部漏尿点压	ALPP
临床实践指南	CPG
毫针深刺腰骶部腧穴治疗	DPSLAT
欧洲泌尿外科协会	EAU
证据决策表	EtD
推荐分级的评估、制订与评价体系	GRADE
指南发展小组	GDG
国际尿控协会	ICS
混合性尿失禁	MUI
最大尿道闭合压	MUCP
尿失禁	UI
急迫性尿失禁	UUI
患者，干预措施，对照措施，结局	PICO
随机对照试验	RCT
压力性尿失禁	SUI
世界卫生组织	WHO
世界针灸学会联合会	WFAS

附 录 C
临床问题汇总

编号	临床问题
1	相比于不做干预或安慰针，常规毫针治疗是否可以使女性尿失禁患者获益?
2	相比于盆底肌功能训练或口服药物，常规毫针治疗是否可以使女性尿失禁患者有同等或更多获益?
3	在盆底肌功能训练或口服药物的基础上，加用常规毫针治疗是否可以使中重度女性尿失禁患者有更多获益?
4	相比于不做干预或安慰针刺，毫针深刺腰骶部腧穴治疗是否可以使女性尿失禁患者获益?
5	相比于盆底肌功能训练或口服药物，毫针深刺腰骶部腧穴治疗是否可以使女性尿失禁患者有同等或更多获益?
6	在盆底肌功能训练或口服药物的基础上，加用毫针深刺腰骶部腧穴治疗是否可以使中重度女性尿失禁患者有更多获益?
7	相比于不做干预，艾灸治疗是否可以使女性尿失禁患者获益?
8	相比于盆底肌功能训练或口服药物，艾灸治疗是否可以使女性尿失禁患者有同等或更多获益?
9	在盆底肌功能训练或口服药物的基础上，加用艾灸治疗是否可以使中重度女性尿失禁患者有更多获益?
10	相比于单纯毫针治疗或艾灸治疗，两种治疗的联合应用是否可以使女性尿失禁患者有更多获益?

参 考 文 献

[1] Joachim W. Thüroff,Abrams P,Andersson K E,et al.EAU guidelines on urinary incontinence[J].European Urology,2011,59(3):387-400.

[2] Chiarelli P,Brown W,Mcelduff P. Leaking urine:prevalence and associated factors in Australian women.[J]. Neurourology & Urodynamics,2015,18(6):567-577.

[3] 庞海玉,朱兰,徐涛,等.基于随机森林算法的中国女性尿失禁发病危险因素研究[J].中华妇产科杂志,2021,56(8):554-560.

[4] Carls C.The prevalence of stress urinary incontinence in high school and college-age female athletes in the midwest: implications for education and prevention[J]. Urologic Nursing, 2007, 27(1):21.

[5] Shamliyan T,Wyman J,Kane R L.Acknowledgments-nonsurgical treatments for urinary incontinence in adult women: diagnosis and comparative effectiveness-National Library of Medicine-PubMed Health[J].Cer,2012.

[6] Richter HE,Burgio KL,Brubaker L,et al. Continence pessary compared with behavioral therapy or combined therapy for stress incontinence[J]. Obstetrics and Gynecology,2010,115(3):609-617.

[7] Dumoulin C,Cacciari L P,Hay-Smith E J C. Pelvic floor muscle training versus no treatment,or inactive control treatments,for urinary incontinence in women[J].Cochrane Database Syst Rev,2018 Oct 4,10(10):CD005654.

[8] Jiang L,Shen XD,He J. Practice bulletin No. 155:urinary incontinence in women[J]. Obstetrics & Gynecology,2015,126(5):66.

[9] Hguyatt G,Doxman A,Jschnemann H,et al.GRADE guidelines:a new series of articles in the Journal of Clinical Epidemiology[J].Chinese Journal of Evidence-Based Medicine,2011,64(4):380-382.

[10] WHO:WHO handbook for guideline development,2nd Edition[M].2014.

[11] 王舢泽,赵吉平,杜世豪,等.《女性尿失禁针灸临床实践指南》临床问题征询调查[J].World Journal of Acupuncture-Moxibustion,2021,31(1):75-78.

[12] 杨超,杜世豪,王舢泽,等.基于改良德尔菲法构建《女性尿失禁针灸临床实践指南》临床问题[J].中国针灸,2022,42(8):927-931.

[13] GRADEpro GDT. The GRADEpro Guideline Development Tool (GDT) is the software used to create Summary of Findings (SoF) tables in Cochrane systematic reviews. Available from:http://community.cochrane.org/help/tools-and-software/gradepro-gdt. Accessed on October 1,2021.

[14] Jaeschke R,Guyatt G H,Dellinger P,et al. Use of GRADE grid to reach decisions on clinical practice guidelines when consensus is elusive[J]. Bmj,2008,337:744.

[15] Solberg M,Alræk T,Mdala I,et al. A pilot study on the use of acupuncture or pelvic floor muscle training for mixed urinary incontinence [J]. Acupunct Med,2016,34(1):7-13.

[16] Emmons SL,Otto L. Acupuncture for overactive bladder: a randomized controlled trial [J]. Obstet Gynecol,2005,106(1):138-143.

[17] 郑慧敏,徐世芬,尹平,等.电针治疗轻中度女性压力性尿失禁的近远期疗效观察[J].世界中西医结合杂志,2015,10(2):191-193+209.

[18] 王彬,唐化勇,王维纲,等.腹针治疗老年女性压力性尿失禁疗效观察[J].辽宁中医杂志,

2011,38(11):2244-2245.

[19] 洪领俊,赵晋,郑国红.电针治疗混合性尿失禁的临床研究[J].针灸临床杂志,2015,31(11):1-4.

[20] Yuan Z,He C,Yan S,et al. Acupuncture for overactive bladder in female adult:a randomized controlled trial[J].World J Urol,2015,33(9):1303-1308.

[21] Solberg M,Alræk T,Mdala I,et al. A pilot study on the use of acupuncture or pelvic floor muscle training for mixed urinary incontinence [J]. Acupunct Med,2016,34(1):7-13.

[22] 严春红,黄慧,俞秋波,等.针刺联合盆底肌训练治疗产后压力性尿失禁临床研究[J].新中医,2019,51(2):217-219.

[23] 李莉,高慧娟,张庆蔚,等.针刺干预辅助盆底肌训练治疗产后压力性尿失禁临床观察[J].云南中医学院学报,2018,41(4):73-75.

[24] 薛宁,夏兆新,朱栋华.腹针疗法加低频电刺激结合盆底肌训练治疗女性压力性尿失禁的临床研究[J].上海中医药杂志,2016,50(8):54-57.

[25] Yun Y J,Kang K W,Yang J N,et al. Effects of acupuncture on urinary incontinence in premenopausal women:Preliminary Study[J].Journal of Korean Acupuncture & Moxibustion Society,2011,28(3):55-71.

[26] 侯文光,明树人,汤康敏,等.电针对轻、中度女性压力性尿失禁的防治效应研究[J].上海针灸杂志,2017,36(8):956-959.

[27] 苏同生,刘保延,刘志顺,等.电针与盆底肌训练治疗女性压力性尿失禁多中心随机对照试验[J].中医杂志,2021,62(5):414-418.

[28] 吴婷.电针联合盆底肌训练治疗女性压力性尿失禁的疗效观察及对盆底功能的影响[D].福建:福建中医药大学,2021.

[29] 王海军,曹玉霞,姬俊强,等."秩边透水道"针法治疗女性压力性尿失禁:随机对照研究[J].中国针灸,2020,40(10):1061-1064.

[30] Liu B,Liu Y,Qin Z,et al. Electroacupuncture versus pelvic floor muscle training plus solifenacin for women with mixed urinary incontinence:a randomized noninferiority trial[J]. Mayo Clin Proc,2019,94(1):54-65.

[31] 谷吕敏,张广香.基于凯格尔运动的三种方法治疗产后压力性尿失禁的临床疗效观察[J].现代实用医学,2018,30(11):1527-1529.

[32] 于春晓,张东磊,陈朝明.电针联合盆底肌训练治疗女性压力性尿失禁 38 例临床观察[J].江苏中医药,2017,49(6):51-53.

[33] Liu Z,Liu Y,Xu H,et al. Effect of electroacupuncture on urinary leakage among women with stress urinary incontinence:a randomized clinical trial[J]. JAMA,2017,317(24):2493-2501.

[34] 王慧.电针和 PFMT 联合索利那新治疗女性中重度混合性尿失禁的比较研究[D].咸阳:陕西中医药大学,2016.

[35] Xu H,Liu B,Wu J,et al. A pilot randomized placebo controlled trial of electroacupuncture for women with pure stress urinary incontinence[J]. PLoS One,2016,11(3):e0150821.

[36] 陈胤希.不同时程电针治疗女性混合性尿失禁的随机对照临床研究[D].北京:北京中医药大学,2016.

[37] 王琼.电针和 PFMT 联合索利那新治疗女性中重度混合性尿失禁的疗效比较[D].长沙:湖南中医药大学,2016.

[38] 程楚.电针与盆底肌训练治疗女性单纯压力性尿失禁临床疗效比较[D].合肥:安徽中医药大学,2016.

[39] 周竞.电针和盆底肌训练治疗女性压力性尿失禁疗效比较研究[D].咸阳:陕西中医药大学,2015.

[40] 河恩惠.基于不同针刺时点的电针治疗压力性尿失禁患者的疗效评价[D].北京:北京中医药大学,2015.

[41] 张淑惟.电针和PFMT联合索利那新治疗女性中重度混合性尿失禁的疗效比较[D].南京:南京中医药大学,2015.

[42] 金良夏(Kim Yangha).电针治疗女性单纯性压力性尿失禁的远期疗效评价[D].南京:南京中医药大学,2015.

[43] 张晓妮.电针治疗女性混合性尿失禁的临床观察[D].南京:南京中医药大学,2015.

[44] 束彦页.电针治疗女性单纯性压力性尿失禁有效性及安全性的临床观察[D].南京:南京中医药大学,2014.

[45] 谢珍囡.艾灸治疗老年女性压力性尿失禁13例临床体会[J].中国老年保健医学,2013,11(6):79.

[46] 高苒,张建英.隔药灸气海穴结合温针灸治疗产后压力性尿失禁27例[J].中医外治杂志,2021,30(4):74-75.

[47] 乔雪奇.热敏灸治疗轻中度女性单纯压力性尿失禁得气与临床疗效相关性的量学研究[D].咸阳:陕西中医药大学.

[48] 萨仁.温灸气海穴治疗中老年女性应力性尿失禁60例临床观察[J].中华中医药杂志,2008(10):944.

[49] 彭爱红.艾灸治疗中风后尿失禁的护理体会[J].世界最新医学信息文摘,2015,15(31):232.

[50] 马晓辉,张爱梅.艾灸治疗中风后尿失禁的临床观察与护理[J].光明中医,2013,28(3):606-607.

[51] 孙玲玲.艾灸治疗中风后尿失禁的临床观察与护理[J].世界最新医学信息文摘,2015,15(36):236+196.

[52] 温敏.艾灸治疗中风后尿失禁患者的护理体会[C]//.2014年河南省中医、中西医结合护理学术交流会论文集.[出版者不详],2014:180-183.

[53] 段立晨,王建强,李清,等.艾条灸治疗卒中后尿失禁的疗效观察[J].中国药物与临床,2020,20(22):3829-3830.

[54] 魏嘉,刘慧林,孙敬青.灸法治疗中风后急迫性尿失禁的临床观察[J].湖南中医药大学学报,2018,38(3):307-310.

[55] 郭文.任脉灸治疗脑卒中后非认知功能障碍性尿失禁的临床研究[D].济南:山东中医药大学,2021.

[56] 吴兆梅,朱才丰,蔡晨星,等.温阳补肾灸在中风后尿失禁病人护理中的应用效果观察[J].护理研究,2019,33(13):2340-2342.

[57] 刘慧林.周德安学术思想与临床经验总结及隔姜隔盐灸神阙法治疗中风后排尿障碍的临床研究[D].北京:北京中医药大学,2011.

[58] 蒋莉.改良型盆底肌训练联合艾灸关元穴治疗女性压力性尿失禁的临床研究[D].北京:北京中医药大学,2020.

[59] 肖春风,李建坤,韦哲,等.艾灸关元穴治疗老年女性压力性尿失禁30例[J].国际中医中药杂志,2013,35(5):442.

[60] 曹静,李燕霞,王琳,等.温针灸联合Kegel盆底康复训练对产后压力性尿失禁的临床研究[J].安徽中医药大学学报,2021,40(3):60-64.

[61] 常宇.温针灸联合盆底肌功能训练治疗肾气虚型压力性尿失禁的疗效观察[D].辽宁:辽宁

中医药大学,2021.

[62] 程蕾,曾薇薇,薛春燕. 温灸八髎穴配合盆底功能锻炼治疗产后压力性尿失禁疗效分析[J].医药前沿,2021,11(32):176-177.

[63] 李秋凤. 任脉灸配合盆底肌训练治疗女性压力性尿失禁的临床观察[D].长春:长春中医药大学,2020.

[64] 廖华薇.隔姜灸配合盆底康复训练治疗压力性尿失禁的疗效[J].中国康复,2013,28(5):381-382.

[65] 刘洁,杨少琴,史影.温针灸八穴结合盆底肌训练治疗女性压力性尿失禁疗效观察[J].中国社区医师,2015,31(8):83-84.

[66] 刘样,胡蓉,袁光辉,等.艾灸配合盆底肌训练治疗产后压力性尿失禁临床观察[J].上海针灸杂志,2018,37(2):192-195.

[67] 彭玉勃,孙丹,黄敬文,等.俞募配穴艾灸法为主治疗女性压力性尿失禁的疗效观察[J].上海针灸杂志,2018,37(7):773-776.

[68] 乔雪奇,安军明.百笑灸联合 Kegel 锻炼法治疗女性压力性尿失禁疗效观察[J].中西医结合心血管病电子杂志,2018,6(9):154-155.

[69] 王安,褚红杰,毛群燕,等.任脉灸联合核心肌群训练改善女性压力性尿失禁的效果观察[J].现代实用医学,2021,33(5):676-678.

[70] 王夏. 艾灸治疗女性轻中度单纯性压力性尿失禁的临床疗效观察[D].咸阳:陕西中医药大学,2017.

[71] 立明,贺艳,余莉菲,等.温针联合盆底肌训练治疗压力性尿失禁临床观察[J].湖北中医药大学学报,2019,21(4):94-96.

[72] 杨晓波,安军明,李书晓,等.热敏灸联合 Kegel 锻炼对轻中度女性单纯压力性尿失禁患者盆底结构及功能改变的可视化研究[J/OL].针灸临床杂志,2021(2):44-48.

[73] 杨晓波,安军明,李羽佳,等.热敏灸联合 Kegel 法治疗轻中度女性单纯压力性尿失禁的临床效果[J].临床医学研究与实践,2020,5(20):143-146.

[74] 臧晓明. 带脉铺姜灸联合盆底肌训练治疗女性轻中度压力性尿失禁的临床观察[D].济南:山东中医药大学,2018.

[75] 张晨,息金波,骆睿翔,等.腹针、艾灸联合盆底肌训练治疗女性压力性尿失禁 60 例临床研究[J]. 江苏中医药,2021,53(7):44-47.

[76] 张鼎.艾灸疗法联合 PFMT 治疗女性轻中度单纯压力性尿失禁的疗效观察[D].咸阳:陕西中医药大学,2017.

[77] 张幸盈.综合护理对女性膀胱过度活动症的效果研究[J].中国农村卫生事业管理,2017,37(6):716-717.

[78] 纪岳军,陈莉莉.针刺联合脐灸治疗老年女性单纯压力性尿失禁的临床观察[J].中国社区医师,2019,35(6):87,89.

[79] 肖桂荣.电针并艾灸治疗女性压力性尿失禁 30 例[J].中医外治杂志,2018,27(4):37-38.

[80] 崔秀敏,赵洁晶,何相成,等.针刺加隔附子灸穴位治疗老年女性尿失禁的临床研究[J].针灸临床杂志,2016,32(5):11-14.

[81] 詹晶文. 针刺结合艾灸治疗女性混合性尿失禁的疗效观察[D].武汉:湖北中医药大学,2016.

[82] 赵洁晶,崔秀敏,卢耀能,等.针刺联合隔附子饼灸治疗老年女性压力性尿失禁临床研究[J].世界中医药,2016,11(5):891-893.