

The role of acupuncture-moxibustion in ovulation induction based on the *Chinese Medicine and Acupuncture-moxibustion Databank*

基于《中医针灸信息库》探讨针灸促排卵

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Abstract

Ovulatory dysfunction refers to absent ovulation or luteal insufficiency. It is commonly seen in women with irregular menstruation or menstrual cycles, especially in those with oligomenorrhea or amenorrhea. Ovulatory dysfunction is considered the single-most frequent cause of female infertility. Clinically, the two major causes of ovulatory dysfunction are polycystic ovarian syndrome (PCOS) and luteinized unruptured follicle syndrome (LUFS). Acupuncture-moxibustion improves ovulation and helps with infertility. Through a systematic review and analysis on relevant literatures in *Chinese Medicine and Acupuncture-moxibustion Databank* over the last decade, this paper summarized the characteristics and pattern of acupuncture-moxibustion points for improving ovulation in order to provide an optimal acupuncture-moxibustion protocol in this regard.

Keywords: Acupuncture-moxibustion Therapy; Acupuncture Therapy; Moxibustion Therapy; Ovulation; Infertility, Female; Bibliometrics

【摘要】 排卵障碍是指无排卵或黄体功能异常,在月经周期及经量紊乱,特别是稀发或闭经时常见,是女性不孕症的主要原因之一。临床实践中所接触到的排卵障碍女性中,多囊卵巢综合征(PCOS)患者所占比例最高,其次为黄素化未破裂卵泡综合征(LUFS)。针灸促排卵是中医治疗不孕症的一大特色。基于《中医针灸信息库》对近10年的相关文献进行系统回顾与分析,总结针灸促排卵选穴的特点及规律,以期探索制定出针灸促排卵的最优化方案。

【关键词】 针灸疗法; 针刺疗法; 灸法; 排卵; 不育, 女性; 文献计量学

【中图分类号】 R246.3 **【文献标志码】** A

Ovulatory dysfunction is absent ovulation or luteal insufficiency. Rather than a medical condition, it is a complex pathophysiological sign due to organic or functional abnormalities resulting from multiple HPG axis-related factors or sites^[1]. Ovulatory dysfunction accounts for 25%-30% female infertility. Other major causes include chronic anovulation, premature ovary failure, decreased ovarian reserve, congenital gonadal dysgenesis, hyperprolactinemia, polycystic ovarian syndrome (PCOS) and luteinized unruptured follicle syndrome (LUFS)^[2]. Clinically, PCOS is the most frequent cause of ovulatory dysfunction (approximately 70%-85%)^[3], followed by LUFS (approximately 25%-43%)^[4].

At present, ovulation induction medications include clomiphene citrate (CC), and gonadotrophin (Gn)

preparations [human menopausal gonadotrophin (HMG), human chorionic gonadotrophin (HCG)], etc. CC is the most widely prescribed drug for ovulation induction; however, it's not recommended for long-term use because of the adverse events including high ovulation induction rate (approximately 80%), low pregnancy rate (35%-40%), HMG/HCG-induced ovarian hyper-stimulation syndrome (OHSS) and multiple gestation pregnancy. In addition, it is not beneficial to restoring the ovarian function^[5]. Acupuncture-moxibustion is a natural, economic and convenient therapy. As early as 1961, Yu J reported that acupuncture resulted in an ovulation rate of 54.4%^[6], followed by an ovulation rate of 81.5% by electroacupuncture (EA)^[7]. In order to come up with an optimal acupuncture-moxibustion protocol for ovulation induction, this paper conducted a systematic review on relevant literatures since 2006 and analyzed the current status of acupuncture-moxibustion for ovulation induction.

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1 Materials and Methods

1.1 Data sources

All data are from the *Chinese Medicine and Acupuncture-moxibustion Databank* (Shen Yi Acupuncture-moxibustion Databank, software copyright registration number: 0980769), which has collected a total of 85 references (2006-2016) on acupuncture-moxibustion for ovulatory dysfunction^[8-92]. Thirteen of these papers have control methods. There are a total of 98 document statistics. All data were searched from the China National Knowledge Infrastructure (CNKI), China Science and Technology Journal Database (CSTJ) and Wanfang Academic Journal Full-text Database (Wanfang). The full texts were downloaded for systematic analysis.

1.2 Search strategy

The search was conducted using the index/key words and titles. The search words included ovulatory dysfunction, PCOS, LUFS, infertility, acupuncture, moxibustion, needling, points, EA and acupuncture combined with Chinese medicine. The search titles included clinical studies and reports on acupuncture-moxibustion for ovulatory dysfunction.

1.3 Inclusion criteria

Randomized controlled trials (RCTs) on ovulation induction efficacy comparison between acupuncture methods, Western medications, Chinese medicine and acupuncture combined with Chinese medicine, and research or clinical reports on efficacy comparison between medications alone and medications combined with acupuncture; sample size ≥ 5 cases, coupled with detailed information on selected points, treatment protocol and definite efficacy with reliable data; and published between 2006 and 2016.

1.4 Exclusion criteria

Literatures not associated with ovulatory dysfunction and acupuncture-moxibustion and literatures regarding acupuncture-moxibustion treatment for infertilities not due to ovulatory dysfunction (but related to fallopian tube, chronic adnexitis, luteal insufficiency or immunological factor, etc.); literatures on case records, experience of well-known doctors, experimental studies, needling and moxibustion methods, studies on acupuncture-moxibustion points, studies on meridians, literature studies, acupuncture anesthesia and acupuncture accidents; literatures that contain simultaneous multiple submissions of one manuscript and data errors; clinical sample size < 5 , literatures that lack clinical efficacy, selected points or treatment methods; and papers on acupuncture-moxibustion for ovulatory dysfunction published before 2006.

1.5 Literature retrieval and screening procedure

The *Chinese Medicine and Acupuncture-moxibustion Databank* yielded 78 034 citations. This paper retrieved 98 (in 85 papers, Figure 1).

2 Results

2.1 Selection of points

Statistical analysis on points used in 85 papers (98 citations) showed that most common ones include Sanyinjiao (SP 6), Guanyuan (CV 4), Zigong (EX-CA 1), Zhongji (CV 3) and Zusanli (ST 36). The top 10 high-frequency points are listed in Table 1.

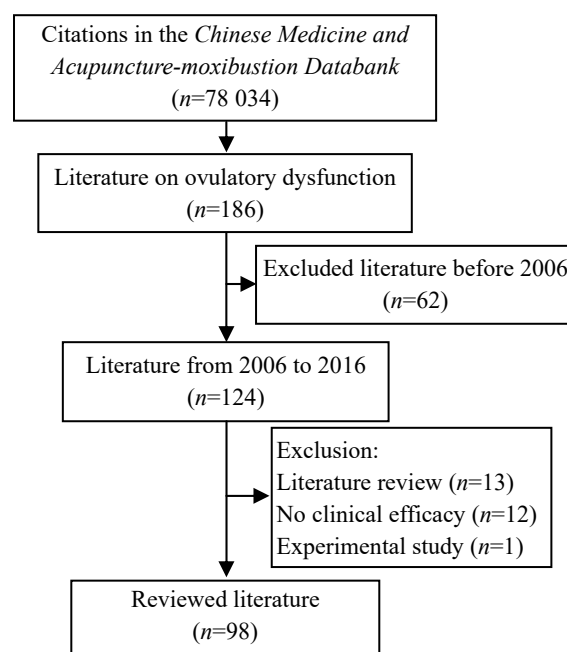


Figure 1. Literature retrieval and screening procedure

Table 1. Common points for ovulatory dysfunction (by frequency)

| Points | Location | Paper | TEC | TC | TER (%) |
|-------------------|---------------|-------|-------|-------|---------|
| Sanyinjiao (SP 6) | Leg (medial) | 89 | 2 286 | 3 170 | 72 |
| Guanyuan (CV 4) | LA | 88 | 2 336 | 3 223 | 72 |
| Zigong (EX-CA 1) | LA | 63 | 1 667 | 2 364 | 70 |
| Zhongji (CV 3) | LA | 60 | 1 463 | 2 074 | 70 |
| Zusanli (ST 36) | Leg (lateral) | 55 | 1 433 | 1 966 | 72 |
| Shenshu (BL 23) | Lower back | 43 | 1 078 | 1 415 | 76 |
| Qihai (CV 6) | LA | 38 | 865 | 1 162 | 74 |
| Taichong (LR 3) | Foot (medial) | 38 | 1 019 | 1 326 | 76 |
| Xuehai (SP 10) | Leg (medial) | 36 | 1 041 | 1 395 | 74 |
| Fenglong (ST 40) | Leg (lateral) | 32 | 781 | 992 | 78 |
| Taixi (KI 3) | Foot (medial) | 27 | 837 | 1 086 | 77 |
| Pishu (BL 20) | Upper back | 21 | 486 | 608 | 79 |

Note: LA=Lower abdomen; TEC=Total eligible cases; TC=Total cases; TER=Total effective rate

2.2 Treatment methods

The most common treatment methods include acupuncture, acupuncture-moxibustion, acupuncture

plus Chinese medicine, moxibustion, EA, thread embedding and point injection (Table 2).

2.3 Timing of acupuncture-moxibustion treatment

Of the 85 papers (98 citations), 42 mentioned specific timing of treatment (by the menstrual cycle). Of the 67 papers on PCOS, 21 reported the treatment started from follicular phase, and the treatment was conducted once a day or every other day to promote follicular growth and development; 43 did not mention the initial treatment time. Of the 18 papers on LUFS, 13 reported the treatment started at the presence of dominant follicles, and the treatment was conducted once a day for 3 consecutive days to promote the release of dominant follicles (Table 3).

Table 2. Common methods for ovulatory dysfunction (by frequency)

| Methods | Paper | TEC | TC | TER (%) |
|-----------------------------------|-------|-------|-------|---------|
| Acupuncture | 60 | 1 659 | 2 207 | 75 |
| Acupuncture plus Chinese medicine | 51 | 1 478 | 1 981 | 75 |
| Moxibustion | 22 | 504 | 723 | 75 |
| EA | 17 | 410 | 607 | 67 |
| Thread embedding | 11 | 242 | 330 | 73 |
| Point injection | 4 | 90 | 117 | 76 |
| Ear point sticking | 3 | 109 | 134 | 81 |
| TDP | 2 | 67 | 76 | 88 |
| Bloodletting | 1 | 30 | 35 | 85 |
| Fire needle | 1 | 43 | 55 | 78 |
| Pricking | 1 | 51 | 61 | 83 |
| Acupuncture plus tuina | 1 | 16 | 20 | 80 |

Note: TEC=Total eligible cases; TC=Total cases; TER=Total effective rate

Table 3. Timing and frequency of acupuncture-moxibustion treatment

| Timing | PCOS | LUFS |
|-----------------|------------------------------------|---|
| Follicle phase | 21 (once a day or every other day) | 5 (once a day in 1 paper; unmentioned in the rest papers) |
| Ovulation phase | 3 | 13 (once a day, for 2-3 consecutive days) |
| Unmentioned | 43 | 0 |
| In total | 67 | 18 |

2.4 Efficacy evaluation

We've conducted a qualitative analysis, because it's impossible to make a meta-analysis due to major differences in intervention methods.

Of the 60 papers on acupuncture combined with Chinese or Western medicine for ovulation induction,

16 reported acupuncture plus Western medicine, 32 reported acupuncture plus Chinese medicine and 12 reported acupuncture plus integrated Chinese and Western medicine. Eighteen papers on LUFS include 14 RCTs and 4 clinical reports. Some RCT studies suggested that acupuncture or acupuncture plus Chinese medicine obtained a better efficacy than HCG alone^[75, 79, 81-82] and some studies have suggested acupuncture plus integrated Chinese and Western medicine obtained a better efficacy than Western medicine alone^[76, 80, 85-86, 92]. CC is the most widely prescribed drug for ovulation induction; however, because of its anti-estrogen effect, CC may cause a thin endometrium and affect embryo transfer despite the growth of dominant follicles. Some patients may develop CC resistance or LUFS. Currently, a large dose HCG is often used for ovulation induction to prevent or minimize the risk of LUFS. However, this may increase the risk of OHSS. Numerous studies have suggested that, compared with Western or Chinese medicine alone, acupuncture combined with medications can promote follicular growth, development and release and at the same time, reduce the risk of OHSS.

As for acupuncture-moxibustion methods, some studies have indicated that warm needling is better than acupuncture alone^[62], thunder-fire moxibustion plus acupuncture is better than acupuncture alone^[72], and needling Zhibian (BL 54) towards Shuidao (ST 28) is better than conventional acupuncture^[66]. Other studies have also suggested that, for PCOS patients, acupuncture based on syndrome differentiation is better than Ashi points in regulating menstruation, endocrine and metabolism^[74].

2.5 Analysis of publication bias

The publication bias has not been analyzed because of the limited test numbers.

3 Discussion

3.1 Selection of points

A variety of points were selected in the included 85 papers (98 citations). According to some studies or reports, the selection of points was based on syndrome differentiation: a distinctive and essential principle in Chinese medical system. The most common points for ovulation induction include Sanyinjiao (SP 6), Guanyuan (CV 4), Zigong (EX-CA 1), Zhongji (CV 3) and Zusanli (ST 36). Sanyinjiao (SP 6), a crossing point of the Liver, Spleen and Kidney Meridians, is an essential point for gynecological conditions. Guanyuan (CV 4) and Zhongji (CV 3) act to reinforce Yuan-primordial qi and supplement essence and blood. Zigong (EX-CA 1) acts to warm and tonify the Yuan-primordial qi. The combination of aforementioned points can tonify the liver and kidney, warm the uterus and regulate Thoroughfare and Conception Vessels. Further studies

need to be done to confirm whether needling Guanyuan (CV 4), Zigong (EX-CA 1) and Zhongji (CV 3) can increase blood supply to ovaries and reinforce the ovary functions. Clinically, in addition to the above major points for ovulation induction, other points are modified according to syndrome differentiation. For example, Fenglong (ST 40) is added for phlegm-dampness in obese patients; Xuehai (SP 10) is added for blood deficiency; and Taichong (LR 3) is added for liver qi stagnation. We hope to come up with an optimal acupuncture protocol for ovulation induction through combined clinical and laboratory studies.

3.2 Common treatment methods

The most common treatment methods (by frequency) include acupuncture, acupuncture plus medicine, moxibustion, EA, thread embedding and point injection.

As for acupuncture plus medicine, 33 papers mentioned acupuncture plus Chinese medicine and 18 mentioned acupuncture plus Western medicine. All papers suggested that acupuncture plus medicine is better than single therapy.

As for EA in 17 cases, different parameters were reported: 8 papers mentioned sparse-dense wave; however, specific parameters vary, for example, <12.5 mA, 5-10 Hz^[31]; 2 Hz/50 Hz^[34]; 0.3 Hz^[75]; no specific parameters except for general sparse-dense wave^[30, 76]. One paper only mentioned EA without specific parameters^[33]. Two papers mentioned EA parameter of 3 Hz, coupled with a tolerable intensity, <5 mA^[15, 32]. Two papers mentioned continuous wave and a tolerable intensity^[37, 61]. One paper mentioned high-frequency continuous wave and a tolerable intensity^[46]. Further clinical and laboratory studies need to be done to compare the efficacy of different EA parameters on ovulation induction and determine a more appropriate method between EA and needling manipulation.

According to ancient literature, moxibustion warms yang qi, unblocks meridians, resolves stasis and tonifies qi. Twenty two papers reported a better efficacy can be achieved in combination with moxibustion.

Thread embedding, point injection and pricking are less commonly used for ovulation induction. For patients with CC resistance and insensitivity to intramuscular injection of HMG, further studies need to be done to confirm whether point injection can improve clinical efficacy and decrease the drug dose.

3.3 Timing of acupuncture intervention

Of the 85 papers (98 citations), 42 mentioned the initial treatment time (by the menstrual cycle). Nine papers mentioned that the treatment started the 5th day after period and was conducted once a day or every other day; however, the treatment course varied and there was no clear information on the time of stopping treatment. Some studies mentioned the treatment started the 6th, 8th, 10th or 12th day after period.

Some studies mentioned that the treatment stopped upon elevation of the basal body temperature^[19, 24].

Of the 67 papers on PCOS, 21 mentioned that acupuncture treatment started from the follicular phase and was conducted once a day or every other day to improve follicular growth and development; 43 papers did not mention the initial treatment time. Of the 18 papers on LUFS, 13 mentioned that acupuncture treatment started from the presence of dominant follicles and was conducted once a day for 3 consecutive days to promote the release of dominant follicles.

For female reproduction, the cyclical variation is closely associated with the hypothalamus-pituitary-ovary (HPO) axis. Ovulatory dysfunction results from multiple factors or abnormalities in multiple sites. Follicular development originates from the primordial follicle to primary follicle transition. The development of primordial follicle initiates before the menstrual cycle. It takes longer than 9 months for primordial follicles to become prenatal follicles. It takes 85 d for a silent primordial follicle to become preovulatory, i.e., 3 menstrual cycles. The final stage of follicular growth takes approximately 15 d and ovulation often occurs 14 d before the next period^[93]. In 1990s, Yu J studied the clinical factors influencing EA for ovulation induction and found that anovulatory patients who have a certain estrogen level or elevated estrogen level after acupuncture respond well to acupuncture^[7]. As a result, it's essential to measure the follicle stimulating hormone (FSH) and estradiol (E_2) levels in patients with ovulatory dysfunction. For patients with a low E_2 level, hormone supplement is beneficial to the efficacy. Large-sample clinical and laboratory studies need to be done to investigate the associate between treatment timing and ovulation induction and determine whether acupuncture is still needed upon ovulation.

3.4 Comparison between acupuncture methods and other therapies

Of the 60 RCT papers, 7 papers^[8, 11, 28, 30, 33, 38, 61] compared the efficacy between acupuncture alone and Western medicine, and the results showed a better efficacy by acupuncture than Western medicine. The other papers reported a better efficacy by acupuncture plus Chinese or Western medicine than Chinese or Western medicine alone. These studies have indicated that, for ovulation induction, acupuncture is better than Western medicine and acupuncture plus medicine is better than acupuncture or medicine alone.

None of the 85 papers reported the occurrence of OHSS. Further in-depth studies need to be done to investigate clinical value and potential of acupuncture in ovulatory dysfunction, because it does not disturb the normal endocrine balance. Numerous papers reported that acupuncture achieved a better efficacy than Western medicine for PCOS; however, the sample size was too small and there were no standard points,

timing, method, course of treatment, pattern identification or high-quality RCTs, the clinical reproducibility, efficacy and credibility needs further evaluation. It's therefore important to conduct double-blind randomized controlled trials and, at the same time, establish standardized criteria in pattern identification and efficacy evaluation. What's more, there are fewer studies on the underlying mechanism of acupuncture in ovulation induction. More scientific and reliable studies are also needed in this regard to guide clinical practice.

Conflict of Interest

The authors declared that there was no potential conflict of interest in this article.

Statement of Informed Consent

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