Special Topic Study

# Effect of ear acupuncture plus injection at Zusanli (ST 36) on shoulder pain and cytokines after gynecologic laparoscopic surgery

耳针配合足三里穴位注射对妇科腹腔镜术后肩痛及细胞因子的影响

Wang Bao-jun (王宝君)<sup>1</sup>, Wu Jia-man (吴家满)<sup>1</sup>, Liu Yan-chang (刘艳嫦)<sup>1</sup>, Zhuo Yuan-yuan (卓缘圆)<sup>2</sup>, Chen Xiao-zhuan (陈小砖)<sup>2</sup>, Li Jin-hua (李金华)<sup>1</sup>

1 Shenzhen Maternal and Child Health Hospital, Guangdong 518028, China

2 Shenzhen Hospital of Chinese Medicine, Guangdong 518033, China

# Abstract

**Objective:** To explore the clinical efficacy of ear acupuncture plus injection at Zusanli (ST 36) in treating shoulder pain after laparoscopic gynecological surgery, and to observe its effect on cytokines.

**Methods:** Two hundred patients with shoulder pain after laparoscopic gynecological surgery were randomized into two groups based on their visiting sequence, 100 cases each. The observation group was intervened by ear acupuncture plus injection at Zusanli (ST 36), and the control group was intervened by oral administration of Ibuprofen, 10 d as a treatment course. The clinical efficacies of the two groups were compared after 2 treatment courses; the visual analogue scale (VAS), present pain intensity (PPI) and 36-item short-form health survey (SF-36) were measured before and after the treatment; the changes of interleukin (IL)-6 and IL-10 after the treatment were also observed.

**Results:** The VAS and PPI scores were significantly changed after the treatment in both groups (both P<0.01). After the treatment, the VAS score in the observation group was significantly different from that in the control group (P<0.05). The component scores of SF-36 were significantly changed after the treatment in both groups (P<0.01); after the treatment, the scores of physical functioning (PF), bodily pain (BP), social functioning (SF), and mental health (MH) in the observation group were significantly different from those in the control group (all P<0.05). The contents of IL-6 and IL-10 dropped significantly after the intervention in both groups (both P<0.01), and the between-group differences were also statistically significant (both P<0.01). The total effective rate of the observation group was higher than that of the control group (P<0.05).

**Conclusion:** Ear acupuncture plus injection at Zusanli (ST 36) can significantly improve the shoulder pain after laparoscopic gynecological surgery, down-regulate the expressions of IL-6 and IL-10, and boost the recovery.

**Keywords:** Acupuncture, Ear; Hydro-acupuncture; Point, Zusanli (ST 36); Shoulder Pain; Laparoscopy; Postoperative Complications; Women

【摘要】目的: 探讨耳针配合足三里穴位注射治疗妇科腹腔镜术后肩痛的临床疗效,并观察其对细胞因子的影响。 方法:将200例妇科腹腔镜术后肩痛的患者按就诊先后顺序随机分为2组,每组100例。观察组采用耳针配合足三 里穴位注射治疗,对照组口服布洛芬治疗。治疗10 d 为一个疗程,治疗2个疗程后比较两组临床疗效及视觉模拟 量表(VAS)、现有疼痛强度(PPI)及生活质量量表(SF-36)评分的变化情况,同时观察两组患者白细胞介素-6(IL-6)和 IL-10的变化情况。结果:两组治疗前后的 VAS 及 PPI 评分均有统计学差异(均 P<0.01)。治疗后,观察组 VAS 评分 与对照组有统计学差异(P<0.05)。治疗前后两组 SF-36各项评分比较均有统计学差异(P<0.01);治疗后,观察组躯 体活动功能(PF),躯体疼痛(BP),社会交往能力(SF)和心理健康(MH)评分与对照组差异有统计学意义(均 P<0.05)。 治疗后两组 IL-6和 IL-10含量均明显下降,与本组治疗前比较均有统计学差异(均 P<0.01),两组间差异亦有统计学 意义(均 P<0.01)。观察组总有效率高于对照组(P<0.05)。结论:耳针配合足三里穴位注射治疗能显著改善妇科 腹腔镜术后患者肩痛的情况,减少细胞因子 IL-6、IL-10的表达,促进病情的恢复。

【关键词】耳针;水针;穴,足三里;肩痛;腹腔镜手术;术后并发症;女性

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E-mail: wujiaman202@163.com

Author: Wang Bao-jun, bachelor, associate chief nurse

Corresponding Author: Wu Jia-man, M.M., associate chief physician.

Shoulder pain is the most common complication after laparoscopic surgery, and its incidence approaches 70%-80%<sup>[1]</sup>. Compared to traditional open surgery, laparoscopic surgery shows obvious advantages, such as smaller incisions, less injury, reduced bleeding, lower incidence of complications, shorter admission duration, and quicker recovery, and thus has now been widely adopted in the treatment of benign gynecologic diseases. However, inflation with carbon dioxide (CO<sub>2</sub>) will increase the intraabdominal pressure and result in elevation of the diaphragm, expansion of the vault of diaphragm, and irritation of phrenic nerve fibers. Like transverse cervical nerve and supraclavicular nerve which are in charge of shoulder skins, the phrenic nerve is also a branch of cervical plexus, so, stimulating it or damage of this nerve will elicit neck shoulder pain. When the intraabdominal stress is excessive, the diaphragm is extremely raised up, and the phrenic nerve is constantly pushed intensely, nerve ischemia and edema will occur, subsequently leading to significant chronic neck shoulder pain. To some patients, the pain is often rated worse than the pain from the actual procedure, and the pain greatly affect the postoperative recovery<sup>[2]</sup>. To ease the postoperative pain, medications are usually used. Although these drugs can reduce the pain to some extent, frequent use of the drugs may cause drug resistance and adverse reactions<sup>[3]</sup>. The undesirable reactions after gynecologic laparoscopic surgery have roused great attention<sup>[4-b]</sup>, and how to reduce the postoperative shoulder pain has also become a research focus<sup>[7]</sup>. To seek a safe and effective scheme, we conducted this study to compare ear acupuncture plus injection at Zusanli (ST 36) with oral administration of a nonsteroidal anti- inflammatory drug for shoulder pain after gynecologic laparoscopic surgery. The report is given as follows.

# **1** Clinical Materials

### 1.1 Diagnostic criteria

The diagnosis of shoulder pain was based on the corresponding criteria in the *Criteria of Diagnosis and Therapeutic Effects of Diseases and Syndromes in Traditional Chinese Medicine*<sup>[8]</sup>: pain around the shoulder, aggravated at night, even disturbing sleep, but swelling is rare; significant shoulder joint dysfunction, with muscular atrophy in severe cases; physical examination may discover extensive subacromial tenderness, the abduction, lifting, external rotation, and adduction of the shoulder joint, as well as back lifting are slightly affected, unable to take off clothes, comb hair, or wash face; X-ray examination is often normal.

# 1.2 Inclusion criteria

Post gynecologic laparoscopic surgery, conforming to the above diagnostic criteria of shoulder pain, without receiving any relevant treatments; able to strictly follow the intervention including acupoint injection and ear acupuncture and accomplish the required course; with good compliance, follow-up allowed; having signed the informed consent form.

### 1.3 Reject and dropout criteria

Shoulder joint tuberculosis, tumor or infection; with poor compliance, or failed to finish the intervention; with a history of vascular or nerve damage in the affected limb; complicated with severe heart, liver or kidney disorders, or unhealed shoulder trauma; having anesthesia contraindications or allergy to the drugs used in this study; at risk for hemorrhage or other acupuncture contraindications; serious adverse reactions during the intervention; unable to finish the intervention and quitted the study.

### 1.4 Statistical method

The IBM SPSS statistics 19.0 was adopted for data analyses in this study. The measurement data with normal distribution were expressed as mean  $\pm$  standard deviation ( $\overline{x} \pm s$ ) and analyzed by paired *t*-test in intra-group comparisons or independent sample *t*-test in between-group comparisons. The measurement data with non-normal distribution were analyzed by rank-sum test. The enumeration data were processed by Chi-square test or rank-sum test. *P*<0.05 indicated a statistical significance.

# 1.5 General data

A total of 200 subjects, admitted to Shenzhen Maternal and Child Health Hospital during September 2014 and September 2015, with shoulder pain after gynecologic laparoscopic surgery, were enrolled. The subjects all started to receive the corresponding intervention at the beginning of the shoulder pain. They were randomized into an observation group and a control group based on the visiting sequence, 100 each. The surgery duration ranged 25-100 min. After the subjects were diagnosed surgery, 108 with hysteromyoma, 49 with ovarian endometrial cysts, 97 with other types of ovarian cysts, and 46 with chronic pelvic inflammatory disease. There were no significant differences in comparing the age, disease duration, and affected side between the two groups (all P > 0.05), indicating the comparability (Table 1).

# 2 Treatment Methods

# 2.1 Observation group

### 2.1.1 Ear acupuncture

Ear acupoints: Sympathetic ( $AH_{6a}$ ), Shoulder ( $SF_{4,5}$ ), Shenmen ( $TF_4$ ), and Subcortex ( $AT_4$ ).

Operation: The patient took a sitting or recumbent position. After the ear was sterilized by 75% alcohol, the practitioner held the ear with the left hand and punctured the acupoints with the right hand by using short-handle filiform needles of 0.16 mm in diameter and 13 mm in length. The needles should be punctured through the cartilage but not the skin on the back, retained for 30 min and manipulated once every 5 min. The treatment was given once per day, with the two

ears treated alternately, 10 sessions as a treatment course.

Crown		Average age	Duration of	Affected side (case)		Operation time	Primary disease (case)			
Group	n	$(\overline{X}\pm s, year)$	$(\overline{x} \pm s, day)$	Left shoulder	Right shoulder	$(\overline{x} \pm s, \text{minute})$	Primary di Hysteromyoma O 58 50	OEC	OOC	CPID
Observation	100	20.5±14.7	1.1±0.5	59	41	56±7.5	58	25	45	17
Control	100	19.8±15.1	1.2±0.4	57	43	52±6.9	50	24	52	29

Table 1. Comparison of the baseline between the two groups

Note: OEC=Ovarian endometrial cysts; OOC=Other ovarian cysts; CPID=Chronic pelvic inflammatory disease

### 2.1.2 Acupoint injection

### Acupoint: Zusanli (ST 36).

Method: The patient took a supine position. After standard disinfection by iodine, the point was punctured by a 5 mL syringe containing the mixture of vitamin B<sub>1</sub> 1 mL [specification: 2 mL (50 mg)] and vitamin B<sub>12</sub> 1 mL [specification: 1 mL (0.25 mg)]. After insertion, the needle was slightly manipulated with lifting-thrusting and twirling skills to produce needling qi sensation (such as numb and distending sensations). Then, the syringe was held still and the medicinal fluid was slowly injected into the acupoint when there was no withdrawal blood, 2 mL for one acupoint. The needle hole was pressed for 1-2 min to prevent bleeding when the injection was finished. The acupoint injection was performed once each day, with the two sides of Zusanli (ST 36) treated alternately, 10 d as a treatment course. The therapeutic efficacy was measured after 2 courses.

### 2.2 Control group

Patients in the control group were prescribed with oral administration of Ibuprofen, a nonsteroidal anti-inflammatory drug, 0.4 g per dose, twice a day, 0.5 h after food.

In the two groups, the intervention was terminated when the pain was gone.

### **3** Observation of Results

# 3.1 Observation items

### 3.1.1 Visual analogue scale (VAS)

Drew a 10 cm straight line on a piece of paper, and marked '0' and '10' respectively on the two ends, 0 standing for no pain and 10 for intensive pain. The patients were asked to mark on the line to represent the pain intensity. The distance from 0 to the mark would be taken as the VAS score.

### 3.1.2 Present pain intensity (PPI)

The PPI divided pain into 6 degrees: no pain, mild discomfort, uncomfortable, unbearable, horrible pain, and extreme pain, respectively scored 0, 1, 2, 3, 4, and 5.

# 3.1.3 36-item short-form health survey (SF-36)<sup>[9]</sup>

The SF-36 was used to measure the quality of life, including physical functioning (PF), physical role functioning (PR), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), emotional role functioning (ER), and mental health (MH). The sum of each component score was considered as the final score. The higher the score, the better the health condition.

### 3.1.4 Cytokines

The enzyme-linked immunosorbent assay (ELISA) was adopted to detect the contents of interleukin (IL)-1 and IL-10 on post-operation day 1 and after the intervention.

# 3.2 Criteria of therapeutic efficacy

It's based on the criteria of therapeutic efficacy of shoulder pain in the *Criteria of Diagnosis and Therapeutic Effects of Diseases and Syndromes in Traditional Chinese Medicine*<sup>[8]</sup>.

Recovery: The shoulder pain was gone, and the shoulder joint function was completely or substantially recovered.

Markedly effective: The shoulder pain was gone, but aching or heaviness occurred on fatigue or change of weather and disappeared without treatment; although it only can reach the level of 10th thoracic vertebra by backward extension, the rest functions were recovered.

Improved: The shoulder pain was mitigated, and the shoulder joint function was improved.

Invalid: There was no improvement after the intervention.

### **3.3 Treatment results**

3.3.1 Comparison of VAS and PPI

Prior to the treatment, there were no significant differences in comparing the VAS and PPI scores between the two groups (P > 0.05). After the treatment, the VAS and PPI scores declined significantly in both groups (P < 0.01). There was a significant difference in comparing the VAS score between the two groups after the treatment (P < 0.05), while the between-group difference in the PPI score was statistically insignificant (P > 0.05), (Table 2).

### 3.3.2 Comparison of SF-36

Prior to the treatment, there were no significant differences in comparing the component scores of SF-36 (P > 0.05). The SF-36 component scores were significantly changed after the treatment in both groups (P < 0.01, P < 0.05); there were significant differences in comparing the scores of PF, BP, SF and MH between the two groups (P < 0.05). The above results indicated that the quality of life in both groups was improved after the treatment, while the improvements of PF, BP, SF and MH were more significant in the observation group than those in the control group (Table 3).

### 3.3.3 Comparison of the contents of IL-6 and IL-10

After the treatment, the contents of IL-6 and IL-10

# Table 2. Comparison of VAS and PPI scores ( $\overline{x} \pm s$ , point)

dropped significantly in both groups (P < 0.01), and the between-group differences were statistically significant (P < 0.01), indicating that the treatment can effectively down-regulate the expressions of IL-6 and IL-10, and the analgesic effect in the observation group was superior to that in the control group (Table 4).

# 3.3.4 Comparison of clinical efficacies

The total effective rate was 95.0% in the observation group versus 75.0% in the control group, and the between-group difference was statistically significant (P<0.05), suggesting that the therapeutic efficacy in the observation group should be superior to that in the control group (Table 5).

Comm			VAS			PPI				
Group	n	Pre-treatment	Post-treatment	<i>t</i> -value	P-value	Pre-treatment	Post-treatment	<i>t</i> -value	P-value	
Observation	100	7.81±1.83	2.21±1.25	25.27	0.00	3.63±0.88	0.93±0.87	21.8189	0.00	
Control	100	7.86±1.91	2.56±1.07	24.21	0.00	3.72±0.82	$1.10\pm0.78$	23.1505	0.00	
<i>t</i> -value		0.19	2.13			0.75	1.45			
P-value		0.85	0.03			0.46	0.15			

#### Table 3. Comparison of SF-36 scores ( $\overline{x} \pm s$ , point)

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Group	п	Time	PF	RP	BP	GH	VT	SF	RE	MH
01	100	BT	41.2±4.1	34.8±3.6	39.2±2.3	56.3±4.1	52.2±3.4	39.2±2.6	53.7±4.7	58.2±2.8
Observation	100	AT	$52.1{\pm}2.9^{1)17)}$	$46.8{\pm}3.1^{2)18)}$	$44.8{\pm}3.1^{3)19)}$	$71.9 \pm 3.7^{(4)20)}$	$65.2 \pm 3.6^{5)21)}$	SFR $39.2\pm2.6$ $53.7\pm4$ $47.2\pm3.1^{6)22}$ $62.7\pm3$ $38.8\pm2.2$ $54.1\pm4$ $48.8\pm2.8^{14}$ $63.1\pm2$	$62.7 \pm 3.1^{7)23)}$	$70.2 \pm 3.9^{8)24)}$
C ( 1	100	BT	40.8±3.4	35.1±2.7	40.1±2.0	54.9±3.9	52.4±2.9	38.8±2.2	54.1±4.1	60.6±2.9
Control	100	AT	53.3±3.1 <sup>9)</sup>	$47.2 \pm 2.2^{10)}$	$45.7 \pm 3.2^{11)}$	72.2±4.2 <sup>12)</sup>	$64.3 \pm 2.7^{13)}$	$48.8{\pm}2.8^{14)}$	$63.1 \pm 2.4^{15)}$	$71.3 \pm 3.2^{16)}$

Note: BT=Before treatment; AT=After treatment; intra-group comparison, 1) t=21.70, P=0.00; 2) t=25.26, P=0.00; 3) t=14.51, P=0.00; 4) t=28.25, P=0.00; 5) t=26.25, P=0.00; 6) t=19.77, P=0.00; 7) t=15.99, P=0.00; 8) t=24.99, P=0.00; 9) t=27.17, P=0.00; 10) t=34.74, P=0.00; 11) t=14.84, P=0.00; 12) t=30.18, P=0.00; 13) t=30.03, P=0.00; 14) t=28.08, P=0.00; 15) t=18.94, P=0.00; 16) t=24.78, P=0.00; compared with the control group after the treatment, 17) t=2.83, P=0.01; 18) t=1.05, P=0.29; 19) t=2.02, P=0.04; 20) t=0.54, P=0.59; 21) t=2.00, P=0.05; 22) t=3.83, P=0.00; 23) t=1.02, P=0.31; 24) t=2.18, P=0.03

### Table 4. Comparison of the contents of IL-6 and IL-10 ( $\overline{x} \pm s, \mu g/mL$ )

Comm			IL-6			IL-10					
Group	n	Before treatment	After treatment	<i>t</i> -value	P-value	Before treatment	After treatment	<i>t</i> -value	P-value		
Observation	100	64.66±5.75	33.53±3.24	47.17	0.00	15.54±2.67	7.42±2.76	21.15	0.00		
Control	100	64.81±5.72	46.42±4.28	25.74	0.00	15.82±2.72	9.86±2.81	15.24	0.00		
<i>t</i> -value		0.18	24.01			0.73	6.19				
P-value		0.85	0.00			0.46	0.00				

### Table 5. Comparison of clinical efficacies (case)

Group	n	Recovery	Markedly effective	Improved	Invalid	Total effective rate (%)
Observation	100	60	28	7	5	95.0 <sup>1)</sup>
Control	100	25	30	20	25	75.0

Note: Compared with the control group, 1) P<0.05

### 3.4 Adverse reactions and dropouts

There were no adverse reactions occurred in the trial. During the whole process, the patients showed a good compliance, without reject or dropout cases.

# 4 Discussion

Shoulder pain is one of the common side effects of gynecological laparoscopic surgery, and it belongs to the Bi-impediment syndrome in traditional Chinese medicine (TCM). According to a study, besides the pain from the operation incision, 63% of the patients complained about subphrenic pain and shoulder pain<sup>[9]</sup>. It's still unclear that what exactly causes shoulder pain after gynecological laparoscopic surgery, though Western medicine holds that the Trendelenburg position in the surgery allows the abdominal fluid (containing CO<sub>2</sub>) to irritate the diaphragm and phrenic nerve<sup>[10]</sup> and makes that body weight of the patient mainly supported by where held by the shoulder brackets, subsequently causing shoulder pain<sup>[11]</sup>. Another explanation says that the abdominal CO<sub>2</sub>-inflation directly or locally produces H<sup>+</sup> which will irritate the phrenic nerve<sup>[12-13]</sup>, inducing pain in the area governed by  $C_4$  spinal cord<sup>[14-15]</sup>. Currently, there are several studies supporting the mechanism of referred pain from  $CO_2$  irritation<sup>[16]</sup>. According to TCM, the pain is from gi-blood stagnation brought by wind, cold and damp pathogens during the operation.

The ear is closely connected with meridians and viscus in both physiology and pathology. Acupuncture at ear points can boost the production of endogenous opioids and other neurotransmitters, contributing to anti-vomiting and analgesia. Therefore, guided by TCM theories, ear points including Sympathetic (AH<sub>6a</sub>), Shoulder (SF<sub>4,5</sub>), Shenmen (TF<sub>4</sub>), and Subcortex (AT<sub>4</sub>) were used in this study. The point Shoulder (SF<sub>4.5</sub>) corresponds to the affected region, and treats the shoulder pain by regulating qi and blood and unblocking meridians. The point Sympathetic (AH<sub>6a</sub>) can release pain and spasm by modulating the autonomic nerve function; the Subcortex  $(AT_4)$  works to adjust the Thoroughfare and Conception Vessels and endocrine; the ear Shenmen  $(TF_4)$  is a critical point in treating various pains, as it can calm the mind, and ease pain and spasm. Meanwhile, acupuncture can enhance the pain threshold, so the body can be more tolerant to pain<sup>[17]</sup>. Moreover, ear acupuncture and stimulation to acupoints will transmit the needling sensations and then affect the sympathetic nerve ends in secreting chemical mediators, consequently producing analgesic effect.

As the He-Sea point of the Stomach Meridian, Zusanli (ST 36) can strengthen the spleen and stomach functions, unblock the Fu organs and resolve phlegm, and regulate qi activities, and thus is an effective point

in treating digestive disorders<sup>[18]</sup>. Acupoint injection combines both acupuncture and medication. Through extending the needling sensations with the stimulation of medications, acupoint injection produces continuous stimulation to the acupoint<sup>[19]</sup>. This trial adopted acupoint injection at Zusanli (ST 36) to regulate and unblock meridians, modulate qi activities, harmonize the stomach and descend the up-flowed qi, and help expel  $CO_2$  out of abdomen to reduce the stimulation to the phrenic nerve.

The increase of serum IL-6 and IL-10 is an important factor in causing shoulder pain, and thus it can mitigate the pain by down-regulating the contents. We observed the serum IL-6 and IL-10 levels 1 d after the surgery and at the end of the intervention, and found that the two approaches, ear acupuncture plus injection at Zusanli (ST 36) and oral administration of Ibuprofen, both brought down the contents, while ear acupuncture plus injection at Zusanli (ST 36) produced a more significant effect, which is possibly one reason for the observation group to produce a better therapeutic efficacy in this trial.

To sum up, ear acupuncture plus acupoint injection at Zusanli (ST 36) is a easy, cost-effective, and safe method in treating shoulder pain after gynecologic laparoscopic surgery. It can be easily accepted by the patients, and effectively improve the symptoms, shorten hospitalization, reduce the cost, and improve the quality of life of the patients, and thus is worth promotion in clinic.

#### **Conflict of Interest**

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

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#### **Statement of Informed Consent**

Informed consent was obtained from all individual participants included in this study.

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Translator: Hong Jue (洪珏)