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# Effect of XiangBin granules on post-operative gastrointestinal function and brain-gut peptides after transabdominal gynecological surgery

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ABSTRACT

*Objectives:* We conducted a prospective clinical randomized single-blind placebo-controlled trial (ChiCTR-TRC-14004156) to observe the effect of XiangBin granules on the recovery of gastrointestinal function and levels of brain-gut peptide motilin (MTL); vasoactive intestinal peptide (VIP); growth hormone releasing peptide-ghrelin, GHRP-ghrelin, and corticotropin releasing hormone (CRH), after transabdominal gynecological surgery.

*Study design:* Patients undergoing gynecologic abdominal surgery were randomly divided in a 2:1 ratio (according to the data of pre-trial which was a small sample randomized trial in gynecology inpatient) into two groups: the larger treatment group taking XiangBin granules, and the smaller placebo group taking Chinese herbal placebo. The aim was to observe anal exhaust time, time to defecation, and the change in level of brain-gut peptide.

*Result:* A significantly shorter time to first postoperative anal exhaust was observed in the treatment group. In the placebo group, the MTL level on the first day after surgery was lower than the preoperative level ($P < 0.05$). In both groups, the GHRP-ghrelin level on the first postoperative day was lower than the preoperative level ($P < 0.05$). In the treatment group, the GHRP-ghrelin level of the third day after surgery was higher than the first day after surgery ($P < 0.05$). The CRH level on the first postoperative day was lower in the treatment group compared to the placebo group ($P < 0.05$).

*Conclusion:* XiangBin granules can effectively promote the recovery of gastrointestinal function after surgery for gynecologic abdomen and promote GHRP-ghrelin and MTL recovery, and reduce the postoperative secretion of CRH.



## Introduction

In recent years, the concept of “fast track surgery” has been gaining currency among the surgical community, the purpose of which is to accelerate the postoperative recovery, shorten the length of hospital stay, and reduce postoperative complications The hallmark of the fast track surgery is the integrated multidisciplinary perioperative approach [1]. Rapid postoperative recovery of gastrointestinal function and early return to normal oral diet is a key component of the fast track surgery approach [2] which, to a large extent, is regulated by brain-gut peptides [3].

Use of traditional Chinese medicine is increasingly being adopted as part of perioperative care [4,5]. In this research we studied the effect of XiangBin granules, a traditional Chinese medicine (TCM) developed recently at our hospital, on the gastrointestinal function and brain-gut peptides after transabdominal gynecological surgery.

## Materials and methods

### General information

The study was conducted between January 2014 and October 2015 at the Guangdong Provincial Hospital of Traditional Chinese Medicine. The study protocol was approved by the Institutional Review Board (IRB) at the Guangdong Provincial Hospital of Traditional Chinese Medicine, and was registered with chictr.org (ChiCTR-TRC-14004156). Written informed consent was obtained from all patients prior to their enrollment in the study.

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*Inclusion criteria*

Inclusion criteria were as follows: adult patients requiring gynecologic surgery under tracheal intubation anesthesia and with an operation time >2 h, either through laparoscopy or laparotomy; and syndrome of qi deficiency as defined by TCM.

*Exclusion criteria*

The exclusion criteria were as follows: patients with malignant tumors; severe cardiovascular, liver, kidney, brain or lung disease; mental illness; those allergic to XiangBin granules; pregnant and nursing women; severe malnutrition (serum albumin <21 g/L or prealbumin <0.10 g/L); patients undergoing a second abdominal surgery with severe adhesive ileus, >400 mL blood loss during surgery; with serious complications; need for a second surgery; concomitant treatment with therapeutic agents known to have a significant effect on the gastrointestinal function. Subjects who participated in other clinical trials with investigational drugs were also excluded. Subjects were not randomly assigned which resulting in data basic;

Study subjects were withdrawn from the study in the event of any serious complication during the observation period, if there was a requirement of second surgery, or incidence of serious allergic reactions or adverse events.

*Study design*

The study was a prospective, randomized, single blind, placebo-controlled clinical trial. The statistical plan was designed for a per protocol (PP) analysis. PEMS 3.1 software for Windows was used to randomly assign the patients to treatment or the placebo group. Patients in both groups received identical standard routine treatment (including antibiotics, maintenance of fluid and electrolyte balance, and nutritional supplements). In addition to the supportive treatment, patients in the treatment group were administered XiangBin granules (ingredients: betel nut, ginseng, radix linderae, agarwood and peachkernel). They were instructed to dilute to 50 mL per bag and drink over half an hour twice a day (9 am and 4 pm), and to stop taking the medication after the first post-surgical defecation.

In addition to the supportive treatment, patients in the placebo group were administered dextrin 1000 g, in a similar way as that of administration of XiangBin granules in the treatment group.

Base line demographic data, medical history, clinical characteristics and treatment details (including surgical details and type of anesthesia) were recorded. Routine pre-operative laboratory investigations were conducted and repeated on day 3 and day 7 after surgery, and at the time of discharge. All patients were closely monitored for any potential adverse events or complications during the observation period.