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Case Control Study

The effect of Modified ShengYangYiwei Decoction on painless gastroscopy

and gastrointestinal and immune function in gastric cancer patients

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Abstract

BACKGROUND

Painless gastroenteroscopy is a widely developed diagnostic and treatment technology in clinical practice. It is of great significance in the clinical diagnosis, treatment, followup review and other aspects of gastric cancer patients. The application of anesthesia techniques during manipulation can be effective in reducing patient fear and discomfort. In clinical work, the adverse drug reactions of anesthesia regimens and the risk of serious adverse drug reactions are increased with the increase in propofol application dose application dose; the application of opioid drugs often causes gastrointestinal reactions, such as nausea, vomiting and delayed gastrointestinal function recovery, after examination. These adverse effects can seriously affect the quality of life of patients.

AIM

To observe the effect of modified ShengYangYiwei decoction on gastrointestinal function, related complications and immune function in patients with gastric cancer during and after painless gastroscopy.

**METHODS** 

A total of 106 patients with gastric cancer, who were selected from January 2022 to September 2022 in Xiamen Traditional Chinese Medicine Hospital for painless gastroscopy, were randomly divided into a treatment group (n = 56) and a control group (n = 50). Before the examination, all patients fasted for 8 h, provided their health education, and confirmed if there were contraindications to anesthesia and gastroscopy. During the examination, the patients were placed in the left decubitus position, the patients were given oxygen through a nasal catheter (6 L/min), the welling needle was opened for the venous channel, and a multifunction detector was connected for monitoring ECG, SPO2, BP, etc. Naporphl and propofol protocols were used for routine anesthesia. Before anesthesia administration, the patients underwent several deep breathing exercises, received intravenous nalbuphine (0.nalbuphine (0.025 mg/kg), followed by intravenous propofol (1.propofol (1.5 mg/kg) until the palpebral reflex disappeared, and after no response, gastroscopy was performed. If palpebral reflex disappeared, and after no response, gastroscopy was performed. If any patient developed movement, frowning, or hemodynamic changes during the operation (heart rate changes during the operation (heart rate increased to > 20 beats/min, systolic blood pressure increased to > 20% of the base value), additional propofol (0.propofol (0.5 mg/kg) was added until the patient was sedated again.

The patients in the treatment group began to take the preventive intervention of Modified ShengYang Yiwei decoction one week before the examination, while the patients in the control group received routine gastrointestinal endoscopy. The patients in the two groups were examined by conventional painless gastroscopy, and the characteristics of the painless gastroscopies of the patients in the two groups were recorded and compared. These characteristics included the total dosage of propofol during the examination, the incidence of complications during the operation, the time of patients' awakening, the time of independent activities, and the gastrointestinal function of the patients after examination, such as the incidence of reactions such as malignant vomiting, abdominal distension and abdominal pain, as well as the differences in the levels of various immunological indicators and

inflammatory factors before anesthesia induction (T0), after conscious extubation (T1) and 24 h after surgery (T2).

#### **RESULTS**

There was no difference in the patients' general information, ASA classification or operation time between the two groups before treatment. In terms of painless gastroscopy, the total dosage of propofol in the treatment group was lower than that in the control group (P<0.05), and the time of awakening and autonomous activity was significantly faster than that in the control group (P<0.05). During the examination, the incidence of hypoxemia, hypotension and hiccups in the treatment group was significantly lower than that in the control group (P<0.01). In terms of gastrointestinal function, the incidences of nausea, vomiting, abdominal distension and abdominal pain in the treatment group after examination were significantly lower than those in the control group (P<0.01). In terms of immune function, in both groups, the number of CD4+ and CD8+ cells decreased significantly (P<0.05), and the number of NK cells increased significantly (P<0.05) at T1 and T2, compared with T0. The number of CD4+ and CD8+ cells in the treatment group at the T1 and T2 time points was higher than that in the control group (P<0.05), while the number of NK cells was lower than that in the control group (P<0.05). In terms of inflammatory factors, compared with T0, the levels of IL-6 and TNF-a in patients in the two groups at T1 and T2 increased significantly and then decreased ( $\overline{P}$ <0.05). The level of IL-6 at T1 and T2 in the treatment group was lower than that in the control group (P<0.05).

#### CONCLUSION

The preoperative use of Modified ShengYangYiwei decoction can optimize the anesthesia program during painless gastroscopy, improve the gastrointestinal function of patients after the operation, reduce the occurrence of examination-related complications.

#### INTRODUCTION

Painless gastroenteroscopy is a widely developed diagnostic and treatment technology in clinical practice. It is of great significance in the clinical diagnosis, treatment, followup review and other aspects of gastric cancer patients. It can also be used to evaluate patients with reflux esophagitis, esophageal cancer, gastroduodenal ulcer, etc[1,2]. The application of anesthesia techniques during manipulation can be effective in reducing patient fear and discomfort<sup>[3]</sup>. Propofol combined with opioids are common clinical drugs for painless endoscopic sedation and anesthetics[4]. On the one hand, in clinical work, the adverse drug reactions and the risk of anesthesia regimens are increased with the increase in propofol application dose; on the other hand, the application of opioid drugs often causes gastrointestinal reactions, such as nausea, vomiting and delayed effects gastrointestinal function recovery, after examination. These adverse can seriously affect the quality of life of patients.

Modified ShengYangYiwei decoction is related to Li Dongyuan's theory, which has the effect of replenishing Qi and rising Yang, clearing heat and detoxification, and removing dampness and turbidity. It has achieved fine effect in the field of digestive endoscopy<sup>[5]</sup>. Therefore, this study observed the treatment interventions of gastric cancer patients and observed the impact on patients' gastrointestinal function, related complications and immune function during and after painless gastroscopy.

# MATERIALS AND METHODS

#### 1 Clinical data

This study was approved by the Medical Ethics Committee of the Xiamen Hospital of Traditional Chinese Medicine (2022-K028-01), and informed consent was signed by all patients.

- 1.1 The inclusion criteria were as follows: ①aged 18-65 years, with a BMI index of 28 kg/m²; ②ASA grade of I-II; and ③no contraindications for gastroscopy.
- 1.2 The exclusion criteria were as follows: ①major cardiovascular and cerebrovascular diseases and failure to cooperate with the examination; ②gravida; ③propofol, opioid

allergy or intolerance; and 4 psychotropic drugs use or abnormal coagulation function before surgery.

#### 1.4 General Information

A total of 106 gastric cancer patients from January 2022 to September 2022 who were selected for painless gastroscopy in Xiamen Hospital of Traditional Chinese Medicine, were divided into a treatment group (n = 56) and a control group (n = 50) by the random number table method. The purpose of painless gastroscopy for the two groups of patients is to conduct health screening and timely diagnosis. The general data between the two groups were not significantly different (P> 0.05) and were comparable. See Table 1.

#### 2 Treatment methods

Before the examination, all patients fasted for 8 h, provided their health education, and confirmed if there were contraindications to anesthesia and gastroscopy. During the examination, the patients were placed in the left decubitus position, the patients were given oxygen through a nasal catheter (6 L/min), the welling needle was opened for the venous channel, and a multifunction detector was connected for monitoring ECG, SPO2, BP, etc.

- 2.1. For the control group, the protocols followed the Expert Consensus on Sedation and Anesthesia in the Diagnosis and Treatment of Digestive Endoscopy in China<sup>[6]</sup>. Naporphl and propofol protocols were used for routine anesthesia. Before anesthesia administration, the patients underwent several deep breathing exercises, received intravenous nalbuphine (0.025 mg/kg), followed by intravenous propofol (1.5 mg/kg) until the palpebral reflex disappeared, and after no response, gastroscopy was performed. If any patient developed movement, frowning, or hemodynamic changes during the operation (heart rate increased to > 20 beats/min, systolic blood pressure increased to > 20% of the base value), additional propofol (0.5 mg/kg) was added until the patient was sedated again.
- 2.2. The patients in the treatment group began oral Modified ShengYangYiwei decoction one week before gastroscopy, with one dose a day, compared with the control

group. The Modified ShengYangYiwei decoction specific composition is "30 g of ginseng, 9 g of atractylodes macrocephala, 9 g of poria, 60 g of astragalus, 15 g of white peony, 30 g of pinellia ternata, 6 g of rhizoma coptidis, 9 g of rhizoma alismatis, 12 g of dried tangerine peel, 10 g of magnolia officinalis, 9 g of rhizoma Notopterygii, 9 g of angelica pubescens, 9 g of fangfeng, 9 g of bupleurum chinense, 5 g of ginger, 6 g of jujube (denuded), 6 g of cohosh, 9 g of kudzu, 9 g of pueraria lobata, 15 g of Shijian Chuan, 12 g of divine koji, and 6 g of raw licorice".Boil and concentrate the drug with 500 mL water to 200 mL, twice in total. Then divide into two portions and take orally after breakfast and dinner.

2.3 Observation indicators: The painless gastroscopy data was recorded ①in the two groups, and these data included the operation time (from the beginning to the end of the examination), awakening time (From the end of the examination to the time when the patient can correctly answer questions such as his name and birthday), autonomous walking time (from the end of the examination to when the patient can go to bed and walk steadily), the total dose of propofol during the examination; ②the incidence of complications (hypoxemia, hypotension, hiccup, *etc.*) during anesthesia; ③ gastrointestinal reactions (nausea, vomiting, abdominal distension, abdominal pain, *etc.*) occurred after examination; and ④T-cell subsets and inflammatory levels at different times.T-cell subpopulation was detected by flow cytometry, and the level of inflammatory factors was detected by biochemical immunoassay.

2.4 Statistical methods: SPSS 22.0 software was used for data analysis. The measurement data are expressed as (x+s), after verifying the normal distribution of indicators in each group and t tests were utilized. The counting data are expressed as [n (%)] using  $\chi^2$  analysis. The F test for analysis of variance was used for comparisons among multiple groups, and the difference was considered statistically significant if P < 0.05.

# **RESULTS**

3.1 Comparison of gastroscopy between the two groups

The operation time of gastroscopy was 4-6 min, without any obvious difference (P>

- 0.05); the awakening time of the treatment group were significantly faster than the control group (P <0.05); the Self-ambulation time of the treatment group were significantly faster than the control group (P <0.05) and for the treatment, the total dose of propofol was was significantly lower than the control group (P <0.01), shown in Table 2.
- 3.2 Comparison of complication occurrence during the examination between the two groups

In the two groups, hypoxemia, hypotension and hiccups were common during painless gastroscopy, and the incidences of these complications were lower than that in the control group. There were significant differences (P < 0.05), as shown in Table 3.

3.3 Comparison of gastrointestinal function after completing the examination in the two groups

After the end of the examination, as shown in Table 4, the incidence of abdominal distension, nausea, abdominal pain, and vomiting in the treatment group was significantly lower than that in the control group (P < 0.05).

3.4 Immune cell numerical values at different times

At T0, there was no significant difference in the CD4+, CD8+, and NK cell numbers between the two groups (P > 0.05). After examination, the CD4+ and CD8+ cells and NK cells at T1 and T2 were significantly decreased (P < 0.05). Comparing the two groups, the CD4+ and CD8+ cells at T1 and T2 were higher than that in the control group(P < 0.05); and NK cells at T1 and T2 were lower than that in the control group(P < 0.05). See Table 5.

3.5 Comparison of inflammatory factors at different times

At the T0 time point, the IL-6 and TNF-a levels were comparable (P> 0.05); after the examination operation, IL-6 and TNF-a at T1 and T2 were significantly higher than before the examination (P < 0.05). With further comparisons between the two groups, IL-6 and TNF-a at T1 and T2 were significantly lower than the control group (P < 0.05), as shown in Table 6.

#### DISCUSSION

Painless gastroscopy is gradually becoming a widely accepted examination means in the clinical diagnosis and treatment of gastric cancer, premalignant diseases, tissue mucosal lesions and other diseases [7,8]. The use of proposol in combination with naborphine painless treatment has become a safer anesthesia regimen commonly used in clinical practice [9,10,11]. However, patients with gastric cancer have a poor physique and are often more prone to anesthesia-related adverse reactions and gastrointestinal-related complications during examination [12]. At present, combining other methods to further reduce the impact of examination on gastrointestinal function in gastric cancer patients has become an area of exploration in current research.

We have summarized the experience in clinical practice for a long time and formed a special treatment agreement of "Modified Shengyang Yiwei Decoction". In this prescription, the whole recipe can replenish the middle and disperse the hair and recover the hair so that the positive qi can be sufficient, and the yang qi can be generated. It can improve the local inflammatory response of the gastric mucosa, regulate the imbalance between cell proliferation and apoptosis, repair the local blood circulation of the gastric mucosa, and improve the pathological state of the gastric mucosa<sup>[13]</sup>. Liang Guoying<sup>[14]</sup> found that Shengyangyi gastric soup could inhibit the expression of NF-kB, Bcl-2, c-myc, and Cyclin-D1 in the gastric mucosa tissue of PLGC rats and regulate gastric mucosal cell apoptosis, thus improving the gastrointestinal function of patients. Zhang Chao et al<sup>[15]</sup> found that it inhibited the conduction of the NF-kB/STAT3 signaling pathway, with significant upregulation of target gene p21 expression, downregulation of Bcl-2 and c-myc, and reduced expression of the inflammatory factors mediated by it. Wang Wei<sup>[16]</sup> found that the application of Shengyangyi gastric soup, and the scattered knot method can promote the wound healing of hyperplastic gastric polyps after gastroscopy and may reduce the degree of their precancerous lesions by reducing the expression of Bcl-2, which has positive significance for the prevention and treatment of hyperplastic polyps and their precancerous lesions. Dong Xiaofeng[17] also found that the intervention treatment of Shengyang Yiwei decoction on PLGC rats can upregulate the expression of p16 and wild-type p53 protein, promote local microvascular proliferation, and improve the structure of patients' gastrointestinal mucosa, and they confirmed that Shengyang Yiwei decoction can effectively block the disease progression of precancerous lesions of gastric cancer. This shows that Modified Shengyang Yiwei Decoction can improve the repair and reproduction of gastric mucosal cells, regulate cell apoptosis, and even inhibit the malignant proliferation of gastric parietal cells. According to the literature, Modified Shengyang Yiwei decoction can increase cerebral blood flow, accelerate the passage of propofol through the blood brain barrier, and thus reduce the induced dose of propofol [18,19]. In this study, the operation time of the two groups of patients undergoing gastroscopy lasted approximately 4 minutes. However, in the treatment group, The total dose of propofol used by patients is less, and after examination, the recovery time and independent walking time of patients were significantly shorter than those in the control group. It may be relatde to that the treatment with ShengYangYiwei Decoction reduced the dose of propofol or increased in β-endorphin secretion [20], which deserves further study.

# CONCLUSION

In summary, the preoperative use of Modified ShengYangYiwei Decoction can optimize the anesthesia program during painless gastroscopy and can significantly reduce the total dose of propofol during the inspection process without affecting the quality of inspection operation, thus shortening the time of awakening and independent activity and reducing the occurrence of hypoxemia, hypotension and hiccups during the inspection process. It improves the gastrointestinal function of patients after operation, reduces the incidence of nausea, vomiting, abdominal distension, abdominal pain and other complications of patients, reduces the inhibition of opioids on the immune system of the body, reduces the inflammatory reaction of patients, is beneficial to the development of painless gastroscopy for gastric cancer patients in clinical practice,

reduces the occurrence of examination-related complications, and improves the compliance and tolerance of treatment. It is safe and feasible.

# ARTICLE HIGHLIGHTS

#### Research background

Gastroscopy is of great significance in the clinical diagnosis, treatment, follow-up review and other aspects of gastric cancer patients, It can also be used to evaluate patients with reflux esophagitis, esophageal cancer, gastroduodenal ulcer, etc. In clinical practice, painless gastroscopy is a widely accepted examination means. The use of propofol in combination with naborphine painless treatment has become a safer anesthesia regimen commonly used in clinical practice. However, patients with gastric cancer have a poor physique and are often more prone to anesthesia-related adverse reactions and gastrointestinal-related complications during examination. At present, combining other methods to further reduce the impact of examination on gastrointestinal function in gastric cancer patients has become an area of exploration in current research.

#### Research motivation

In order to explore a new intervention plan to optimize the anesthesia drug plan for painless gastroscopy and reduce the anesthesia related complications and postoperative discomfort of patients during the examination.

#### Research objectives

Modified ShengYangYiwei decoction is related to Li Dongyuan's theory, which has the effect of replenishing Qi and rising Yang, clearing heat and detoxification, and removing dampness and turbidity. It has gradually achieved fine effects in the field of digestive endoscopy. Therefore, this study observed the treatment interventions of gastric cancer patients and observed the impact on patients' gastrointestinal function, related complications and immune function during and after painless gastroscopy.

#### Research methods

A total of 106 gastric cancer patients from January 2022 to September 2022 who were selected for painless gastroscopy in Xiamen Hospital of Traditional Chinese Medicine, were divided into a treatment group (n = 56) and a control group (n = 50) by the random number table method.

Before the examination, all patients fasted for 8 h, provided their health education, and confirmed if there were contraindications to anesthesia and gastroscopy. During the examination, For the control group, the protocols followed the Expert Consensus on Sedation and Anesthesia in the Diagnosis and Treatment of Digestive Endoscopy in China<sup>[6]</sup>. The patients in the treatment group began oral Modified ShengYangYiwei decoction one week before gastroscopy, with one dose a day, compared with the control group. The Modified ShengYangYiwei decoction specific composition is "30 g of ginseng, 9 g of atractylodes macrocephala, 9 g of poria, 60 g of astragalus, 15 g of white peony, 30 g of pinellia ternata, 6 g of rhizoma coptidis, 9 g of rhizoma alismatis, 12 g of dried tangerine peel, 10 g of magnolia officinalis, 9 g of rhizoma Notopterygii, 9 g of angelica pubescens, 9 g of fangfeng, 9 g of bupleurum chinense, 5 g of ginger, 6 g of jujube (denuded), 6 g of cohosh, 9 g of kudzu, 9 g of pueraria lobata, 15 g of Shijian Chuan, 12 g of divine koji, and 6 g of raw licorice".Boil and concentrate the drug with 500 mL water to 200 mL, twice in total. Then divide into two portions and take orally after breakfast and dinner.

Observation indicators: The painless gastroscopy data was recorded ①in the two groups, and these data included the operation time, awakening time, autonomous walking time, the total dose of propofol during the examination; ②the incidence of complications during anesthesia; ③gastrointestinal reactions occurred after examination; and  ${}^4\Gamma$ -cell subsets and inflammatory levels at different times.T-cell subpopulation was detected by flow cytometry, and the level of inflammatory factors was detected by biochemical immunoassay.

#### Research results

There was no difference in the patients' general information, ASA classification or operation time between the two groups before treatment. In terms of painless gastroscopy, the total dosage of propofol in the treatment group was 115.36 ± 8.17, which was lower than that in the control group 146.21 ± 10.17 (P<0.05), and the time of awakening and autonomous activity was significantly faster than that in the control group (P<0.05). During the examination, the incidence of hypoxemia, hypotension and hiccups in the treatment group was significantly lower than that in the control group (P<0.01). After examination, on terms of gastrointestinal function, the incidences of nausea, vomiting, abdominal distension and abdominal pain were significantly lower than those in the control group (P<0.01). In terms of immune function, in both groups, the number of CD4+ and CD8+ cells decreased significantly (P<0.05), and the number of NK cells increased significantly (P<0.05) at T1 and T2, compared with T0. The number of CD4+ and CD8+ cells in the treatment group at the T1 and T2 time points was higher than that in the control group (P<0.05), while the number of NK cells was lower than that in the control group (P<0.05). In terms of inflammatory factors, compared with T0, the levels of IL-6 and TNF-a in patients in the two groups at T1 and T2 increased significantly and then decreased (P<0.05). The level of IL-6 at T1 and T2 in the treatment group was lower than that in the control group (P<0.05).

# Research conclusions

The preoperative use of Modified ShengYangYiwei decoction can optimize the anesthesia program during painless gastroscopy, improve the gastrointestinal function of patients after the operation, reduce the occurrence of examination-related complications.

# Research perspectives

At present, combining other methods to further reduce the impact of examination on gastrointestinal function in gastric cancer patients has become an area of exploration in current research.

The preoperative use of Modified ShengYangYiwei decoction can improve the gastrointestinal function of patients after the operation. This trial showed that the expression levels of IL-6 and TNF- $\alpha$  at T1 and T2 were significantly lower than those in the control group, preventing the excessive inflammatory response in the body, and the potential antitumor effect is also worth further study.

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