

Clinical Research for the Treatment of Tubal Obstructive Infertility by Fallopian Tube Recanalization Combined with Traditional Chinese Medicine

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Abstract

Objective: To observe the clinical curative effect of Fallopian Tube Recanalization combined with Traditional Chinese Medicine and to explore the mechanism of Traditional Chinese Medicine in the treatment of Tubal Obstructive Infertility.

Method: We selected 180 patients with Tubal Obstructive Infertility and randomly divided them into 3 groups, each group contained 60 subjects. The subjects of the first group received treatment of Fallopian Tube Recanalization combined with Traditional Chinese Medicine, the second group received Fallopian Tube Recanalization alone and the third group received Traditional Chinese Medicine alone. Then we observed the success rate of each group according to their Fallopian tube patency rate, pregnancy rate and Fallopian tube re-adhesion formation rate.

Result: (1) The success rate of the first group was 81.7%, while that of the second group was 78.3%, and 56.7% for the third group. There was a significant difference between the first group and the third group, as well as the second group and the third group ($P < 0.05$). (2) One year's follow-up after treatment showed the pregnancy rate (defined as numbers of pregnancy over numbers of successful recanalization procedures) of the first, second and third group were 65.3%, 53.2% and 64.7% respectively. Although there was no significant difference between these 3 groups, the pregnancy rate of the two groups which applied Traditional Chinese Medicine was higher than the group which applied recanalization procedure alone. (3) One year after treatment, there were 5 Fallopian tube re-adhesion cases in the first group, 12 cases in the second group and 5 cases in the third group, the re-adhesion rate was 10.2%, 25.5% and 14.7% respectively. There was a significant difference between the first group and the second group ($P < 0.05$).

Conclusion: Interventional Fallopian Tube Recanalization can increase the rate of patency of occluded Fallopian tube, while Traditional Chinese Medicine can decrease post-operational tubal re-adhesion formation rate and facilitate pregnancy. The two treatments can be combined to treat Tubal Obstructive Infertility.

Keywords: Tubal obstructive infertility; Fallopian tube recanalization; Traditional Chinese medicine; Interventional radiography; Blood stasis

Introduction

Tubal Obstructive Infertility is a common gynecological disease which causes 40-60% of infertility in women [1]. How to open the obstructed Fallopian tube and keep its function and lasting patency is a key research area in clinical gynaecological medicine, and how to improve intrauterine pregnancy rate is the end objective of treating tubal obstructive infertility. We selected randomly some patients with tubal obstructive infertility as research subjects and treated them with Fallopian Tube Recanalization or Traditional Chinese Medicine or the combination of these two, so as to evaluate the curative effects of these treatments. We did relative analysis of the results, and then further explored the mechanism of Traditional Chinese Medicine in treating tubal obstructive infertility.

Clinical Data

Source of subjects

All the subjects were selected from the patients who underwent interventional Fallopian Tube Recanalization in the Department of Interventional Radiology of the Second Affiliated Hospital of Baotou Medical College during Jun 2006 - Jun 2012.

Criteria for selecting subjects

All the subjects should be healthy and has been diagnosed with

tubal obstructive infertility by salpingography, they should also have the following four requirements: The uterus and adnexa were normal and the follicle developed well under ultrasound test; The six sex hormones were in normal range. The test of reproductive system of the male partner was normal; The ability to adhere to recommended treatment and the desire to achieve pregnancy in the near future.

Criteria for eliminating subjects

The subjects had a disease which counter indicated pregnancy, or had one of the following conditions: Infertility not caused by tubal diseases; Receiving other treatments other than the three treatments mentioned above; inability to follow the instructions of the health provider.

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General information

We selected 180 patients with tubal Obstructive infertility as our research subjects according to the criteria for subjects' selection. They aged from 22-41 years old, average age was 31.36 ± 3.78 , the duration of infertility was 1-12 years, and average infertility duration was 4.53 ± 1.88 years, with 58 primary infertility and 122 secondary infertility. In this study, there were 333 obstructed Fallopian tubes, among them 101 interstitial obstruction, 74 isthmic obstruction, 62 ampullary obstruction, 96 fimbrial obstruction with adhesion with surrounding tissues. We divided the subjects into 3 groups evenly and carried out statistical analysis about their age, duration of infertility, type of infertility and site of obstruction. There was no remarkable difference between the 3 groups ($P > 0.05$) and they were comparable.

The first group was given Fallopian Tube recanalization combined with Traditional Chinese Medicine; the second group was given Interventional Fallopian Tube recanalization and the third group Traditional Chinese medicine alone.

Method

Instruments

X-ray machine: Philips FD10 of Netherland, FTC-900 of Cook Incorporated, Bloomington, USA. Contrast agent: Omnipaque 300 mg/ml.

Therapies

Interventional tubal recanalization: For patients who undergo this treatment, it requires to exclude other causes of infertility, such as the woman's ability to ovulate, make sure that she has a healthy reproductive tract and her male partner produces enough viable sperms, and she has no infection of the reproductive system. The operation should be arranged 3-7 days after the last menstruation under informed consent of the patient. Preoperative preparation such as iodine allergy test, antispasmodic medication injection, etc should be executed. During the operation, help the patient to take lithotomy position, give routine vulva disinfection, expose the cervical with the help of speculum, disinfect the vagina and cervical thoroughly, then perform tubal recanalization procedures. Patency is confirmed when contrast agent introduced through the small catheter in the occluded tube is visualized via X-ray machine. After the operation, gentamicin injection 80,000 units, dexamethasone injection 5 mg, chymotrypsin 4000 units diluted with 20 ml normal saline are irrigated into the Fallopian tube. The patient should take oral antibiotics and abstain from sexual intercourse for 2 weeks.

Traditional chinese medicine treatment: Traditional Chinese Medicine specialist prescribes traditional Chinese medicine based on the syndrome differentiation, including oral herbal medicine and abdominal herbal hot compress. The oral herbal medicine is based on the traditional patency herbal decoction which combines peach kernel, safflower *carthamus*, rhizoma *cyperi*, red-rooted *salvia*, rhizoma *spagani*, zedoary, *rheum officinale*, rhizoma *alimatis*, *angelica sinensis*, *asarum*, etc. These herbal medicines should be decocted in 100 ml water. The patient drinks the decoction twice a day, and stops to take it during menstruation. The herbal medicines used for abdominal hot compress include: manis pentadactyla, spina *gleditsiae*, liquidambar formosana hance, *angelica sinensis*, root of common peony, radix *bupleuri*, poncirus trifoliolate, field pennycress, sargent gloryvine etc. Put these herbal medicines into a sac, steamed for 30 minutes, then put the sac on the lower abdomen, once every night, stop during menstruation.

After 3 menstrual cycle's treatment, check the level of patency of the Fallopian tube, instruct the patient to try to conceive.

Evaluation of the curative effect

Level of patency is confirmed in 3 menstrual cycles after treatment. Success is defined by at least patency of one side of the Fallopian tubes, incomplete patency or still occluded Fallopian tubes are considered failure. Then calculate the patency rate, the pregnancy rate in 1 year's follow-up. If the patient has not conceived in 1 year after recanalization procedure despite the confirmed patency of the Fallopian tube, re-check contrast enhanced imaging, record the cases of incomplete patency or re-occlusion. Calculate re-adhesion formation rate.

Statistic method

Put all the information in a data base; apply the software SPSS13.0 for statistical processing. Measurement date is analyzed by t-test, enumeration data is analyzed by Chi-square test. $P < 0.05$ means having statistical significance.

Result

Patency was determined by introducing liquid or contrast agent through the small catheter to the Fallopian tubes for imaging. The success rate of the first group was 81.7% (49/60), the second group 78.3% (47/60), and the third group 56.7% (34/60). Statistical test $X^2 = 11.022$, $P < 0.005$, which showed there was a significant difference between the 3 groups. Then we compared the difference of every 2 groups. There was no significant difference between the first and the second group, but there was significant difference between the first group and the third group, as well as the second group and the third group ($P < 0.0125$).

One year's follow-up after treatment showed the pregnancy rate of the three groups was 53.3% (32/60), 41.7% (25/60), and 36.7% (22/60) respectively. When eliminating the failed cases, defined as rate of pregnancy number over success number of recanalization procedures, the pregnancy rate of the first group was 65.3% (32/49), the second group 53.2% (25/47), the third group 64.7% (22/34). Although there was no significant difference between each group, the pregnancy rate of the two groups which applied Traditional Chinese Medicine was higher than the group which applied recanalization procedure alone.

The patients who have not conceived in one year after successful recanalization procedure have received X-ray imaging to check the Fallopian tubes. There were 5 re-adhesion formation cases in the first group, 12 cases in the second group, 5 cases in the third group, the re-adhesion rate of each group was 10.2% (5/49), 25.5% (12/47), 14.7% (5/34) respectively. There was a significant difference between the first group and the second group ($P < 0.05$).

In this study, 2 patients who received Traditional Chinese Medicine treatment alone for 14 months have conceived successfully, this was also counted in the numbers of pregnancy.

Discussion

Tubal occlusion is usually caused by bacterial, viral and mycoplasma infections. Inflammatory mural exudation of the Fallopian tubes can cause local stenosis, granuloma formation, lumen adhesion, inflammatory embolus, and eventually lead to tubal occlusion. Because of increased incidence of sexually transmitted diseases, pelvic inflammatory disease and endometriosis and frequent intrauterine operations, the incidence of tubal occlusion has the tendency to increase year by year. There have been a number of treatments in the clinical

setting, such as antibiotics, tubal liquid irrigation, tubal recanalization, Traditional Chinese Medicine treatment etc; every method has its own strength and weakness.

Tubal recanalization is an effective, simple and safe interventional therapy [2-4]. It was first reported in 1985 by Platia, later Thurmand invented a series of instruments used for Fallopian tubal recanalization and strongly promoted this technique, the Schmitz-Rode and other doctors have improved the recanalization apparatus and achieved better results [5]. In 1992 China has imported this technique, since then many radio interventional specialists have ameliorated the recanalization instruments gradually, and have achieved similar patency rate of that of western countries [6]. But this therapy is merely a mechanical opening of the Fallopian tubes, and only corrects the inner anatomy of the lumen of the Fallopian tubes; the cause of chronic inflammatory disease has not been solved. Although anti-infection and anti-adhesion methods are adopted during recanalization procedure, the effect against chronic inflammation is limited, leading to increased re-adhesion formation rate and decreased fecund ability [5]. For this reason, how to maintain lasting patency of the Fallopian tubes, prevent adhesion formation, increase pregnancy rate, and decrease ectopic pregnancy is a much discussed medical problem. In addition, interventional tubal recanalization is not very effective for distal tubal occlusion, hydrosalpinx and adhesion with the surrounding tissues.

Traditional Chinese medicine has its unique advantages and promising potential in treating tubal obstructive infertility. It is based on syndrome differentiation and believes that 'blood stasis and internal resistance' are the underline cause of tubal obstructive infertility and has made classification of different etiologies [7]. Many traditional Chinese medicine specialists have emphasized the treatment on resolving 'blood stasis', applying medications to improve blood circulation and resolve blood stasis in accordance with the patient's constitution. In order to improve the efficiency of the treatment, they usually combine internal (oral) medications and external therapies such as compress, enema and acupuncture, etc [8]. Modern pharmacological studies showed that traditional Chinese herbal medicines with properties to promote blood circulation and resolve blood stasis have the effect to ameliorate hemodynamics and blood rheology, as well as anti-inflammatory effect. When applying these herbal medicines on patients with tubal obstructive infertility, they can also promote topical micro-circulation, resolve lumen adhesion, prevent inflammation, and accelerate the healing and repairing process of scarring tissues, increase luminal peristalsis, so as to facilitate the opening of the occluded Fallopian tubes. The lacking of established therapeutic standards, the unknown mechanism of some herbal medicines, the longer duration of treatment, as well as inconvenient administration routes are the factors which have adversely affected the effect of the traditional Chinese medicine treatment.

Nowadays more and more specialists have combined traditional Chinese with other modern techniques to treat tubal obstructive infertility, such as radio interventional treatment combined with TCM, tubal liquid irrigation combined with TCM, etc [9]. Nian Dingfang et al. has reported that tubal recanalization combined with TCM can increase the success rate of patency and pregnancy [10]. We designed this study in order to analyze about the clinical significance of tubal recanalization procedure, traditional Chinese medicine treatment and the combination of these two therapies in treating tubal obstructive infertility.

The herbal medicines used on the subjects of this study were prescribed exclusively by experienced associate chief traditional

Chinese medicine practitioner. The dosage was increased or decrease according to the general condition of the patient. The oral herbal medicine is based on traditional 'tubal recanalization decoction' which is mainly applied to treat tubal obstructive infertility caused by 'blood stasis'. The effect of this decoction has been proved by modern pharmacological research [11]. Peach kernel can decrease blood vessel resistance, improve hemodynamics. Safflower can stimulate uterus, and has remarkable analgesic effect. *Rhizoma cyperi* has inflammatory, analgesic, sedative effect. Red-rooted salvia can dilate peripheral blood vessels, improve micro-circulation. *Rhizoma spaganii* can decrease platelet count, prevent embolus formation. Zedoamy has bacteriostatic effect. *Rheum officinale* has anti-bacteria, anti-inflammatory and immuno-regulatory effect. *Rhizoma alismatis* can induce diuresis and alleviate edema; Angelica can prevent embolus formation effect. Asarum has inflammatory and sedative function. Abdominal hot compress with herbakl medicine can promote topical blood circulation and lymphatic circulation. The combination of these herbal medicines can resolve blood stasis, open meridian, promote detoxication of the liver and regulate the flow of internal energy of the body.

As we have observed, traditional Chinese medicine has its unique advantages in improving the patient's symptoms and physical signs, as well as in relieving abdominal pain and regulating menstrual cycles. This may be related to the fact that certain herbal medicines can promote pelvic blood circulation, improve the nutritional condition of pelvic tissue, facilitate the absorption of inflammatory exudation and regulate immune system's function. In addition, traditional Chinese medicine has obvious curative effect in opening distal tubal obstruction.

In conclusion, interventional tubal recanalization procedure is effective in achieving patency of occluded Fallopian tubes, but it has the disadvantage of high post-operational adhesion formation rate and low pregnancy rate. Traditional Chinese medicine is effective in improving topical symptoms and physical signs, but it has lower patency rate. The combination of traditional Chinese medicine combined with mechanical opening of the occluded tubes can treat both the root cause and the symptoms of the disease, so as to satisfy the need of more patients with infertility.

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