Treatment of tubal pregnancy using comprehensive interventional methods

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Summary

Objective: To investigate the efficacy of combined interventional methods in treatment of tubal pregnancy. *Materials and Methods:* One hundred sixty-two patients with tubal pregnancy were enrolled in this study. In all patients, the feeding uterine artery at affected side was perfused with methotrexate (MTX), followed by occlusion using gelatin sponge. Nineteen patients were also treated by perfusion of MTX in ovarian artery at affected side which partially participated in blood supply. Seven patients received direct puncture perfusion of MTX under B ultrasound guidance. Four cases received perfusion of MTX through fallopian tube. After surgery, the serum beta-human chorionic gonadotropin (β-HCG) level was regularly detected, and B ultrasound was used to monitor the pelvic mass change. For 33 patients with fertility requirement, hysterosalpingography (HSG) was conducted after menstruation restoration. *Results:* Tubal pregnancy was terminated in 160 patients (98.76%), with inefficacy in two patients (1.23%) who were treated by surgery. HSG showed tubal patency in 27 patients. Tubal obstruction was found in the other six patients. After recanalization, three cases were unobstructed, with obstruction in other three cases. Fifteen patients achieved intrauterine pregnancy after six to 17 months from surgery. *Conclusions:* Comprehensive interventional treatment can prevent internal bleeding caused by failure of many conservative treatments, improve the indication and success rate of treatment, and preserve the complete fallopian tube.

Key words: Tubal pregnancy; Interventional treatment; Efficacy.

Introduction

Tubal pregnancy is a common acute abdomen in obstetrics and gynecology department and acute serious hemorrhea caused by the rupture or abortion from tubal pregnancy can endanger the life of the pregnant woman. There are many causes of tubal pregnancy: inflammation and surgery are the main factors, in addition, chlamydia trachomatis infection [1], abnormal change of estrogen 17β-estradiol level [2], and low level expression of adrenomedulin (ADM) [3] are closely related to pathogenesis of tubal pregnancy. Traditional treatment methods are surgery or expectant treatment, but fallopian tube ablation of most affected side can influence reproductive capacity of the patient; expectant treatment fails due to bleeding in most cases. Constant research on how to treat tubal pregnancy safely and effectively and retain the fertility of the patient as much as possible is therefore important. Interventional therapy, which has small trauma, is perfect and accurate and has low complication, and has been introduced in clinical practice in obstetrics and gynecology [4].

The goal of this study was to explore how to use synthetic interventional therapy to treat tubal pregnancy. From 1997 to this day, the authors selected 162 cases with tubal pregnancy diagnosed in their hospital to perform synthetic interventional therapy, such as perfusion and embolism in uterine artery and/or perfusion and chemotherapy in fallopian tube.

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Materials and Methods

Clinical data

From October 1997 to the present, the authors selected 162 patients with tubal pregnancy in their hospital that were finally diagnosed synthetically by serum β-HCG , type-B ultrasound, and clinical symptoms and were willing to accept interventional therapy. Their age range was 20-42 years, mean age was 32.6 years , and there were 99 cases with tubal pregnancy in the right side and 63 cases in left side. There were 126 unmarried patients, 138 who did not bear children, and 24 who had an intrauterine device (IUD). Among the total, there were seven cases that had repeated tubal pregnancy, three cases that had mistakenly performed induced abortion, one case that had mistakenly performed drug abortion, and one case that had combined rheumatic heart disease and mitral valve stenosis. There were 25 cases combined with peritoneal cavity bleeding, but with stable vital signs. Suppressed menstruation time was 27-69 days; white cell count in each was more than 3.5×10^9/l, all patients had different degrees of abdominal pain, there was maximum diameter line of 8.0 × 4.9 cm for pelvic cavity mass, and maximum diameter line of 4.1 × 2.5 cm for the blastocyst determined by type-B ultrasound. There were 27 cases with hydrops in pelvic cavity and the widest anteroposterior diameter in the hydrops in pelvic cavity was 3.8 cm. The authors performed culdocentesis in 16 patients, extracting 1.5 - five ml of unclotted blood; among the total, there was one case combined with 1.8 ml hydrops in liver-kidney interspace and 0.3 ml hydrops in spleen-kidney interspace at the same time, there was one case combined with 3.9 ml seroperitoneum, and beta-human chorionic gonadotropin (β-HCG) value in serum was 67.8 ~ 491.6I U/l (normal value < 15 IU/l). This study was conducted in accordance with the declaration of Helsinki and with approval from the Ethics Committee of Tianyou Hospital Affiliated to Wuhan University of Science and Technology. Written informed consent was obtained from all participants.

Figure 1. — A female 26-year-old patient. As a catheter could not be inserted into uterine artery, due to patient refusal, rami viscerales of internal iliac artery in affected side was embolised. There was fetal heart beat two days after the operation as detected by ultrasonic color Doppler and 50 mg MTX were instilled to terminate the pregnancy with cannula from the cervix to the opening of fallopian tubes in affected side.

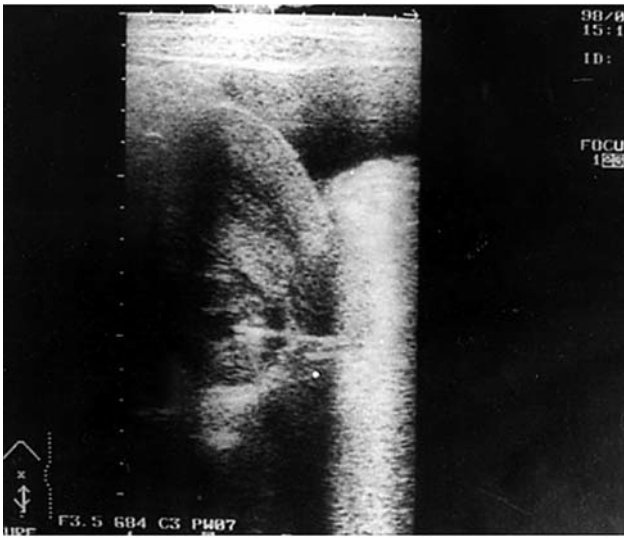

Figure 2. — A female 29-year-old patient. There was fetal heart beat two days as detected by ultrasonic color Doppler diagnostic system. The gestational sac was directly punctured and filled with 30 mg MTX to terminate the pregnancy; the mass in pelvic cavity was absorbed after six months.

Method

The authors adopted the Seldinger technique through femoral artery, and inserted 5F super-smooth Cobra catheter via the uterine artery in affected side, and performed an arteriography to confirm abnormal staining in the area of fallopian tubes; this group of cases were divided into three types of vessels signs according to the manifestation of the angiography. They instilled MTX + physiological saline at three ml/min with constant pressure pump, type I-II patients used 60-~100mg MTX, and type III patients used 100~120mg MTX. After the completion of drug instillation, the authors used gelfoam particulate for embolization of uterine artery and performed an arteriography at the opposite side for 30 patients randomly; the result did not show any change, similar to affected side by comparison. There were six cases that required instillation chemotherapy as well, who showed thickening arteria ovarica because of contrast media reflux when performing arteriography in uterine artery in affected side. There was one case in which the embolism of ramus splanchnicus of internal iliac artery was performed, because the catheter could not be inserted in the uterine artery as the patient resolutely rejected operative treatment. There was a fetal heart beat after two days as detected by ultrasonic color Doppler, therefore 50 mg MTX were instilled to terminate the pregnancy with intubation from cervix to the opening of fallopian tubes in affected side (Figure 1). There was still a fetal heart beat in one patient two days after the operation by ultrasonic color Doppler, and the gestational sac was directly punctured and instilled with 30 mg MTX under the induction of type-B ultrasound to terminate the pregnancy. The mass in pelvic cavity was absorbed after six months (Figure 2).

Treatment after the operation and monitoring indexes

The authors used three mg of formyltetrahydrofolate (CF) intramuscularly 12 hours after the operation, once every four hours for four times total and also prescribed anti-inflammatory hydration treatment for three days. Serum β-HCG values were assessed every week three days after the operation until it decreased to normal level. Type-B ultrasound was performed each week to compared the results with that before the operation in order to understand some conditions such as the diminution of the mass, blastocyst deformities, and intra-abdominal hemorrhage absorption. For patients who had fertility requirements and agreed to accept hysterosalpingography (HSG), it was performed at three to five days after resumption of menses to normal level, to understand whether fallopian tubes were unobstructed or not; recanalization was performed in obstructed patients.

Evaluation of therapeutic effect

Cure: clinical symptoms disappeared; patients who had had internal hemorrhage stopped bleeding, β-HCG in serum decreased to normal level, the mass in pelvic cavity disappeared or shortened, and the menses restored to normal level. Failed cases: clinical symptoms did not disappear or were aggravated, serum β-HCG in did not decrease to normal level or was continuously higher than normal, the mass in pelvic cavity enlarged, and internal hemorrhage appeared again and required open abdominal surgery.

Statistics sampling

The authors selected 162 patients with tubal pregnancy in their hospital, which were finally diagnosed synthetically by β-HCG in serum, type-B ultrasound and clinical symptoms, and that were willing to accept interventional therapy. The age range was 20-42 years and mean age was 32.6 years . They randomly collected 29 patients from these as pre-therapy group; 22 patients were collected from these and were rechecked at the sixth month after the operation and assigned as post-treatment six months group; 16 patients from these were randomly rechecked at the 12th month after the operation and assigned as post-treatment 12 months group.

Figure 3. — A female 31-year-old patient. Suppressed menstruation time was 52 days with lower quadrant pain. A mass of 2.4 × 2.7 cm can be seen in the left annex by ultrasonic color doppler. Uterus showed even staining in parenchymal phase of left uterine arteriography and without remaining positive signs, which belongs to type I angiographic change.

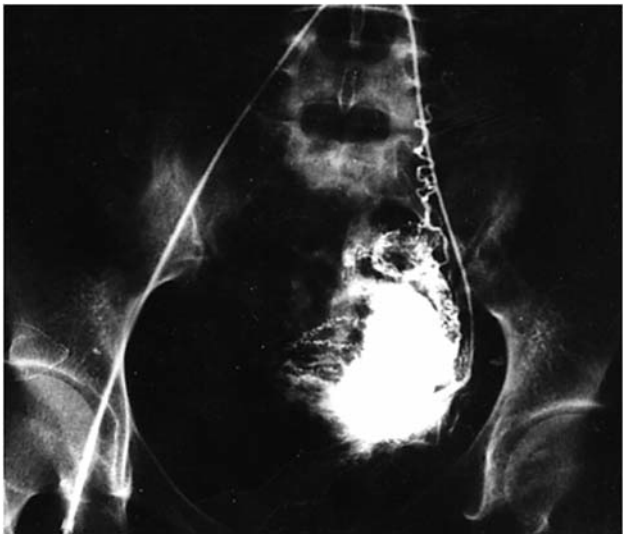

Figure 4. — A female 29-year-old patient. Suppressed menstruation time was 66 days and she appeared left lower quadrant pain. A mass of 4.9 × 4.1cm can be seen in the left annex by ultrasonic color doppler and hydrops in pelvic cavity was also detected; 2.2 ml of unclotted blood was extracted through culdocentesis. There was a lamellar floss staining in parenchymal phase of left uterine arteriography and without integrated gestational sac, which belongs to type II angiographic change.

At follicular phase, four to five ml fasting venous blood was taken from the patients, serum was separated, and stored at -20°C. E_2, LH, and FSH kits were utilized according to the manufacturer's instructions. A radioimmunoassay and KH-6020 γ immunity counter were also utilized.

Statistical analysis

SPSS 17.0 statistics software was used and each parameter was expressed as ± s; t-test was used for the comparison between pretherapy and post-treatment. There was statistical significance between the difference if $p < 0.05$.

Results

Angiographic image of tubal pregnancy

Tubal pregnancy has extensively altered vascularization: angiography showed that the gestational sac originated from tubal branches of the uterine and ovarian arteries that can contribute to the sac's vascularization, and in few cases also from anastomotic branches. They were divided into three types according to angiographic signs in 162 patients and according to the comparison of the arteriography of uterine artery in opposite side in 30 patients. Type I: no obvious positive signs in 15 cases (9.25%) (Figure 3); Type II: tubal branches from the uterine artery at pregnancy side were thickened, with no blood-supply vessels to gestational sac, and there were stained filaments in parenchyma phase, and complete gestational sac was not visible in 26 cases (16.05%) (Figure 4); Type III: tubal branches from uterine artery at pregnancy side was clearly thickened, arteriole branches originated from the tubal branches that supplied

Figure 5. — A female 32-year-old patient. Uterine artery in pregnant side and its tubal branches clearly increased as shown by right uterine arteriography. There is a characteristic gestational sac vessel sign indicated by the arrow. Small vessels that winded the periphery of gestational sac wall and profluvium as well as bleeding caused by embryonic sac rupture can be seen at the bottom of the picture, which belong to type III angiography change.

the gestational sac, there were distinctive vessel signs of gestational sac in advanced stage of artery and parenchyma phase; a filament was clearly stained, the shape was round, the border was irregular, the staining was even or uneven,

Table 1. — *Comparison of sex hormone levels between pre-therapy and post-treatment ($\bar{x}$±s).*

	n	E_2 (pg/ml)	LH (mIU/ml)	FSH (mIU/ml)
Pre-therapy	29	68.18±11.53	6.23±1.35	4.78±1.30
Six months after treatment	22	64.34±12.61	6.16±1.39	4.80±1.34
Twelve months after treatment	16	67.09±11.25	6.25±1.42	4.72±1.33

there was small vessel showing round encasement in periphery gestational sac's wall, the manifestation was similar to double ring echo of tubal pregnancy under type-B ultrasonic, and these characteristics were seen in 121 cases (74.69%) (Figure 5).

Treatment effectiveness

The number of cured patients were 160 (160/162, 98.76%) in which clinical symptoms disappeared quickly after treatment; the time for serum β-HCG level to decrease to normal levels was from six to 41 days (mean 14.4 ± 11.51). The haematocele in pelvic cavity was completely absorbed at 28-66 days postoperatively; the masses in pelvic cavity were completely absorbed 11-31 days after the operation. Menses returned to normal 26-43 days postoperatively (mean 29.78 ± 7.1). Two cases (2/162, 1.23%) did not achieve successful results, even if serum β-HCG decreased postoperatively, nonetheless it still continued to be higher than normal value. The mass in pelvic cavity had a tendency to increase as shown by type-B ultrasound and consequently surgery was performed due to fallopian tube rupture and bleeding that continued postoperatively for 12 to 16 days. There were many infarcted placental, trophoblastic, and necrotic tissues discharged through bleeding, as confirmed by sampling.

Unobstructed fallopian tubes and pregnancy conditions

Out of 41 patients who had fertility requirements, 33 patients underwent HSG three to five days after first menses. The results showed that in 31 patients, the fallopian tube was canalized and in two patients, recanalization was performed due to obstruction; of these two, one patient achieved recanalization while the other still presented distant obstruction. There were 15 patients who achieved intrauterine pregnancy six to 17 months postoperatively.

Effects on sex hormone level

There was no significant difference between six month post-treatment and pre-therapy with respect to the change of E_2 ($p = 0.427$), LH ($p = 0.975$), FSH ($p = 0.997$). There was no significant difference between 12 month post-treatment and pre-therapy with respect to the change of E_2 ($p = 0.942$), LH ($p = 0.999$), and FSH ($p = 0.987$) (Table 1).

Discussion

Tubal pregnancy is a commonly encountered disease in obstetrics and gynecology department; more than 98% of ectopic pregnancy occur in fallopian tubes [5, 6], especially in the ampulla. Once pregnancy ruptures, bleeding amount is often extensive, shock can appear in short time, which can cause infertility and can even endanger the patient's life. It is the main causes of death of pregnant woman during gestation, because ectopic pregnancy cannot be diagnosed and treated in time. Therefore, it is very important to search for a method which can integrate diagnosis and treatment, cause smaller trauma, and that can offer a reliable therapeutic effect and maintain reproductive organs intact.

In this study, 162 patient angiogram results were grouped and selective uterine artery cannulation chemotherapy and embolotherapy were performed, combined with MTX injection with traditional techniques either per abdomen or vagina with ultrasound guidance at the same time. Out of 162 patients, 160 patients were cured. In patients who had fertility requirements, 33 patients underwent HSG postoperatively and the results showed that there were 31 patients with unobstructed fallopian tubes; among the total, there were 15 patients that achieved an intrauterine pregnancy within 17 months postoperatively. There was no obvious change between six and 12 postoperatively with respect to preoperative E2, LH, and FSH.

This experiment indicates that this method has higher achievement ratio, fewer complications, and less effect on normal fertility as well as on sex hormone levels in treating tubal pregnancy.

Tubal pregnancy was divided into operative and non-operative treatment. Non-operative treatment mainly included expectant treatment and medicinal treatment. Expectant treatment was only suitable for a part of low-risk tubal pregnancies and the effective difference was significant. Emma *et al.* [7] found that achievement ratio was between 48%-100% due to the difference of selected criteria. Medicinal treatment can avoid surgery and postoperative complications but has strict indications, and is only suitable for ectopic pregnancy in early stage and patients who have no prior pelvic inflammation. Hossam *et al.* [8] performed the comparison between single dose and double dose MTX and the results showed an achievement ratio of 72% and 79%, respectively. Initiated fallopian tube rupture was found in 3.8% and 2.5%, respectively.

MTX treatment can include some risks such as allergy, embryopathy, and so on [9]. Compared with non-operative treatment, achievement ratio of synthetic interventional therapy occurs in 98.77%; there are only 1.23% of patients who have fallopian tube rupture, and side-effects are due to local application drugs. Treatments are mainly divided into open abdominal surgery, peritoneoscopic surgery, and interventional therapy. Many open abdominal surgeries are radical operations which resect fallopian tubes in affected

side. Many peritoneoscopic operations are conservative embryo removal techniques. A report [10] abroad showed that the application of conservative surgery with the peritoneoscope is more common than open surgical procedures, which has become main therapeutic method for tubal pregnancy.

Fallopian tubes in affected side is resected or conservative surgery treatment with peritoneoscope and can leave a scar in fallopian tubes, which not only brings higher injury to the body, but can be easily complicated with bleeding, infection, ureteral injury, intestinal obstruction, fallopian tubes stenosis and so on, which also have an effect on fertility. Shavit *et al.* [11] reported that ectopic pregnancy can recur after salpingectomy. Although single foramen peritoneoscope has more advantages than traditional peritoneoscope treatment, it still includes complication such as the bleeding, incisional hernia, and so on [12].

To achieve acute ischemia and necrosis of ectopic nidation embryo, the present authors adopted metaphase nonpermanent gelfoam particulates to embolize the uterine artery. It not only made internal hemorrhage decrease or stop, but also avoided having to open the abdomen while it preserved integral fertility of the patients. Blockage of supply blood is an effective therapeutic tool for the hemorrhage after cesarean section, which has been described since 1952; achievement ratio of treating hemorrhaging patients after childbirth and cesarean section by ligating uterine artery is up to 90% [13]. In 1970s, Farrer-Brown *et al.* used uterine artery embolism to treat postpartum hemorrhage [14].

According to arteriography change of uterine artery of 162 patients with tubal pregnancy in affected side and the comparison with arteriography of 30 cases among the total in normal side randomly, the present authors found that the uterine artery sends out slight tubal branches from fundus of uterus to supply fallopian tubes, which is the main blood supply vessel for tubal pregnancy and has anastomotic branches with the uterine artery. When tubal pregnancy occurs, because fertilized ovum imbeds in fallopian tube lumen, trophoderm splits and increases, the chorion grows and filament vessels form; when the arteriography of uterine artery was performed, contrast media enters into abundant filament vessel, it can be seen there are agglomerate or lamella staining of floss vessel in the area of fallopian tubes besides the uterus in parenchymal phase of the angiography, which shows characteristic vessel sign when performing arteriography. It can provide reliable evidence for tubal pregnancy to further clear diagnose and selectivity uterine artery cannulation.

Interventional therapy is gradually being accepted and adopted as a newly emerging therapeutic tool. For treating fallopian tube diseases, the basic operation is selective fallopian tube cannulation. Platia and Krudy [15] are the first to report interventional therapy of fallopian tubes. Traditional interventional therapy is mainly introduced by ultrasound per abdomen, per vaginal, X-rays, uteroscope, and so on, which uses selective fallopian tube cannulation and injects certain drugs such as MTX and mifepristone on affected side of fallopian tubes to locally treat tubal pregnancy. However traditional interventional therapy has some risks such as inflammatory blockage and perforating of fallopian tubes, which are important reasons that cause infertility [16]. The present data showed that the recovery rate for synthetic interventional therapy was 98.76%. Synthetic treatments reports that incidence rate of general side-effects caused by MTX is 21% and that of topical drug administration is 2%. Topical drug administration aim is to inhibit or kill filament nutrient cell, cause ectopic embryo growth to pause, necrotize, and disappear, and provoke lesser injury to fallopian tube tissue as much as possible, and protect fallopian tubes from obstruction. In the present study, the authors selected different treatment protocols according to the different angiographic results, enured that the drug arrived to fallopian pregnancy site directly and quickly, decreased drug collateral side-effect, while improving the therapeutic effect at the same time.

Shalev *et al.* reported that less than eight weeks of gestational is the optimal time for topical drug infusion therapy [17]. The present authors previously thought that drug filling therapeutic effect is certain if embryo sac diameter was less than 3.0 cm. There were 25 patients suffering from tubal pregnancy and then they developed abortion or rupture, 14 patients whose blastocyst diameters were more than 3.0 cm, and 22 patients whose gestation weeks were more than eight, therefore the authors increased MTX dose moderately for patients with type III angiographic change: gestational sac in this type may implant in mucous membrane deep layer or lamina muscularis, blood supply is abundant, and filament tissue vitality is strong. This difference may provide evidence for confirming the doses in chemotherapeutics.

There are several factors influencing the effect in applying synthetic interventional therapy: the first factor is to confirm the indication of the operation, the second factor is that ductus arteriosus need insert to uterine artery by ultraselection, the third is to control the dose of the drug. These factors need to be studied further. In addition, the feasibility of the operation again and the best time also need to be studied. Chen *et al.* [18] shows that the effect of injecting etoposide is better than that of MTX under the guidance of the peritoneoscope, which widen our thread when we select injecting drug.

In this study, the authors used clinical research regarding ultraselection uterine arterial cannulation to diagnose and treat tubal pregnancy, which can solve the problem of intra-abdominal hemorrhage, decrease toxic and side-collateral side-effects of injecting MTX, preserve the integrity of fallopian tubes and fertility function of the patient, and establish a new way to diagnose tubal pregnancy and synthetic expectant treatment.

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