Chinese Medicine
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A Four-Step Protocol for Improving the Effects of Clomiphene in Patients with Ovulatory Dysfunction Infertility

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Cohort Description
A total of 110 patients diagnosed with female infertility were enrolled in this two-wing comparison study. These 110 were then randomly divided into two groups – a treatment group of 60 and a comparison group of 50. Within the treatment group, the median age in these patients was 29.17 ± 3.50 years, and the median duration of infertility was 4.23 ± 1.81 years. Forty-four cases suffered from primary onset infertility and 16 cases from secondary infertility. In the comparison group, the median age was 29.60 ± 3.23 years, and the median duration of infertility was 4.10 ± 1.75 years. Thirty-eight of these cases suffered from primary onset infertility and 12 cases from secondary onset infertility. Therefore, for the purposes of this study, these two groups were deemed statistically comparable in terms of age, disease duration, and type of infertility.

Treatment Method
All members of the treatment group received the following four-step protocol for the regulation of menstruation with Chinese medicinals.

Menstrual period: In order to warm the menses and scatter cold, quicken the blood and transform stasis, Shao Fu Zhu Yu Tang (Lesser Abdomen Dispel Stasis Decoction) with additions and subtractions was administered:

- Yan Hu Suo (Rhizoma Corydalis), 10g each
- Chi Shao (Radix Rubra Paeoniae)
- Chuan Xiong (Rhizoma Chuanxiong)
- Gan Cao (Radix Glycyrrhizae (Gan Cao), 9g each
- Xiao Hui Xiang (Fructus Foeniculi), 12g
- stir-fried Ru Xiang (Olibanum), 6g each
- Rou Gui (Cortex Cinnamomoni), 5g

Post-menstrual period: In order to increase essence and boost the kidneys, nourish the blood and regulate menstruation, Yi Shen Tiao Xue Jang (Boost the Kidneys & Regulate Menstruation Decoction) with additions and subtractions was administered:

- Shu Di (cooked Radix Rehmanniaae)
- Shan Zhu Yu (Fructus Corni)
- Nu Zhen Zi (Fructus Ligustri Lucidi)
- Tu Si Zi (Semen Cuscutae)
- Rou Cong Rong (Herba Cistanchis), 12g each
- Dang Gui (Radix Angelicae Sinensis)
- stir-fried Shan Yao (Radix Dioscoreae)
- stir-fried Xiang Fu (Rhizoma Cyperi)
- Can Cao (Radix Glycyrrhizae), 10g each

Midcycle: In order to boost the kidneys and course the liver, quicken the blood and free the flow of the network vessels, Shu Gan Huo Xue Tang (Soothe the Liver & Quicken the Blood Decoction) with additions and subtractions was administered:

- Bai Shao (Radix Alba Paeoniae)
- uncooked Mai Ya (Fructus Germinatus Hordei)
- Shi Xian Chuan (Squama Manitis)
- Lu Jiao Plan (Cornu Cervi), 12g each
- Dang Gui (Radix Angelicae Sinensis)
- Dan Shen (Radix Salviae Miltiorrhizae), 10g each
Chai Hu (Radix Bupleuri)
Gui Zhi (Ramuulus Cinnamomi)
Can Cao (Radix Glycyrrhizae), 9g each
Shui Zhi (Hirudo), 6g

Premenstruum: In order to warm yang and boost the kidneys, Wen Yang Yi Shen Tang (Warm Yang & Boost the Kidneys Decoction) with additions and subtractions was administered:

Tu Si Zi (Semen Cuscutae)
Zi Shi Ying (Flouritum)
Xian Ling Pi (Herba Epimediim)
She Chuang Zi (Semen Nnidii)
Shu Di (cooked Radix Rehmanniae)
Sang Ji Sheng (Herba Taxillii), 12g each
Xiang Fu (Rhizoma Cyperi)
Can Cao (Radix Glycyrrhizae), 9g each
Dang Cui (Radix Angelicae Sinensis), 10g
Ba Ji Tan (Radix Morindae Officinalis), 15g

When it says "with additions and subtractions" above, it means that these base formulas were modified according to each patient's presenting patterns.

Both groups also were administered 50-100 milligrams of clomiphene per day beginning on day five and continuing for five days. One month equaled one course of treatment, and results were analyzed after three such courses.

Study Outcomes

In the treatment group, there were a total of 152 menstrual cycles with 127 ovulations (83.6%). In addition, there was a conception rate of 41.7%. In the comparison group, there were 137 menstrual cycles with 102 ovulations (74.5%) and only a 22% conception rate. Thus there was no marked difference in the total ovulatory rate between these two groups, but there was a significant difference in the rate of conception. In addition, Insler scores were tabulated for all members of both groups before and after treatment. The Insler score is a way of scoring the quality of vaginal mucus at ovulation. A score (out of 12) for the quality of cervical mucus, gauged by scoring each of the following from 0 to 3:

1) The cervix should be open, and the volume of mucus should be good. Although every woman will be different for both these parameters, they will be consistent in one woman from ovulation to ovulation.
2) The mucus should be clear, watery, and stretchy (Spinnbarkheit).
3) The mucus should produce a complete "ferning" pattern when it is allowed to dry on a microscope slide. The first two criteria vary at ovulation in different women (so anything above a score of 9 or 10 can be normal), but the same woman should achieve the same cervical score from one ovulation to the next.

As Table 1 shows, the mean Insler score in the group that received both the Chinese medicinals and clomiphene was much higher after treatment than that of the group that only received the clomiphene. In addition, there was also a significantly thicker endometrium in the treatment group after treatment than in the comparison group. And, finally, after treatment, the menstrual cycle was normal in 47 patients (78.3%) in the treatment group compared to only 30 cases (60%) in the comparison group.

Discussion

According to the authors of this study, ovulatory dysfunction is a main cause of female infertility, and clomiphene citrate is commonly used to induce ovulation in such women. However, the conception rate with this drug does not correspond to what one would like. Unfortunately, using the four-step method of regulating menstruation does not achieve as high a rate of ovulation as does clomiphene. Therefore, the authors of this study decided to combined the use of clomiphene with this four-step, menstruation-regulating method. During menstruation, the sea of blood is full and exuberant, and it is the time for its discharge. During that time, the use of blood-quickening and stasis-transforming medicinals benefits corpus luteum by promoting the complete shedding of the endometrial lining. After menstruation, the blood is consumed and damaged, and the sea of blood is empty and vacant. Now, medicinals for increasing the essence and boosting the kidneys not only increases serum estrogen levels but also improves the cervical mucus, thus making it easier for the sperm to penetrate it. It also promotes the growth of the endometrial lining. Mid-cycle, yin transform into yang. Therefore, boosting the kidneys and coursing the liver, quickening the blood and freeing the flow of the network vessels can promote the maturation and the expulsion of the ovum. It also insures a healthy environment for the zygote to implant in the endometrium. During the premenstruum, kidney yang qi gradually becomes effulgent, and eventually, double yang transforms into yin. At this time, the use of medicinals to warm and supplement kidney yang along with kidney yin-supplementing medicinals further promotes the proper environment for the zygote to implant and develop. Not only does the combination of clomiphene with this four-step method improve the conception rate, it also has no adverse side effects. Therefore, the authors believe this method achieves relatively good therapeutic effects.