



Contents lists available at ScienceDirect

European Journal of Integrative Medicine

journal homepage: www.elsevier.com/eujim



Research paper

Effects of Korean herbal medicine on pregnancy outcomes of infertile women aged over 35: A retrospective study

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ARTICLE INFO

Article history:

Received 23 May 2016

Received in revised form 10 July 2016

Accepted 11 July 2016

Available online xxx

Keywords:

Korean herbal medicine

Advanced maternal age

Pregnancy outcome

Female infertility

Cost analysis

Adverse events

ABSTRACT

Introduction: Delaying childbearing has led to an increased incidence of age-related female infertility. The interest in herbal medicine as an option for fertility care extends to many countries. The aim of this study was to evaluate the outcome of Korean herbal medicine treatment for women with infertility aged ≥ 35 years by calculating the clinical pregnancy and live birth rate through a retrospective analysis.

Methods: A retrospective analysis was carried out using computerized charts for 270 infertile women, over the age of 35 years receiving Korean herbal treatment from the Happaesem Korean Medicine Clinic, between 2011 and 2012. The main outcome measures were clinical pregnancy and live birth rates. Secondary outcome measures included the predictors of pregnancy success and treatment period/cost until pregnancy was achieved.

Results: Our results revealed that clinical pregnancy and live birth rates after Korean herbal treatment were 44.4% and 26.3%, respectively, in totality, 49.0% and 30.0%, respectively, in the 35–39 years group, and 31.4% and 15.7%, respectively, in the 40–46 years group. The clinical pregnancy rates were 44.0% in the Korean herbal treatment group and 43.4% in the Korean herbal treatment + western treatment group. The live birth rates were 23.5% in the Korean herbal treatment group and 31.3% in the Korean herbal treatment + western treatment group. The mean treatment duration was 11.26 ± 5.02 weeks and average cost for Korean herbal treatment was $\$1320 \pm 600$.

Conclusions: Our retrospective study suggests that management of infertile women ≥ 35 years with Korean herbal treatment can be effective and economical.

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1. Introduction

Today, women all over the world tend to delay childbearing due to postponement of marriage, professional pursuits, or educational achievements. The birth rate for women over the age of 35 years has risen continuously. It is reported that the birth rate for women ≥ 35 years has increased from approximately 35 births per 1000 women in 1990–61.5 in 2014 [1], and about 20% of women have their first child after the age of 35 in the USA [2]. These demographic shifts towards delayed childbearing may have led to the increase in age-related female infertility. According to a classic report on age-related infertility, the percentage of married

women who remain childless increases progressively: 6% at age 20–24 years, 9% at age 25–29 years, 15% at age 30–34 years, 30% at age 35–39 years, and 64% at ages above 40 years [3]. Additionally, a prospective fecundability study has indicated that the infertility rate increases from 13 to 14% for women aged 27–34 to 18% for women aged 35–39 [4].

Most women who need fertility treatment are referred for costly conventional management with assisted reproductive technologies (ART) such as in vitro-fertilization (IVF). It is reported that the average cost of a single fresh IVF cycle is \$4950 (USD), ranging from \$1800–\$13,000 in 32 middle and high-income countries [5]. However, the success rates of ART start declining from the age of 35 years [6]. According to a large-scale research study, women aged 35–39 years and 40–44 years undertaking ART had only 24% and 11.2% probability, respectively, of conceiving, compared with 31.4% for women aged 30–34 years [7]. Therefore,

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<http://dx.doi.org/10.1016/j.eujim.2016.07.002>

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ART could become a more serious financial burden for women with infertility aged 35 years and above.

Meanwhile, the use of traditional herbal medicine as an alternative for fertility care is becoming more widespread due to failure to conceive [8], and the efficacy of traditional herbal medicine is increasingly being recognized [9,10]. According to a systematic review, patients receiving herbal treatment had a 1.74 times higher probability of pregnancy compared with those receiving western medicine therapy [10]. Women aged ≥ 35 years are showing an interest in receiving herbal medicine treatment because of the low probability of success of ART. However, very few studies have investigated the effectiveness of herbal treatment in women with infertility aged ≥ 35 years.

Therefore, the aim of this study was to evaluate the outcome of Korean herbal medicine (KHM) treatment for women with infertility aged ≥ 35 years by calculating the clinical pregnancy and live birth rate through a retrospective analysis. In addition, we sought to investigate the predictors of pregnancy with KHM treatment. Medical costs per successful pregnancy were also evaluated.

2. Materials and methods

2.1. Subjects

The study participants were selected from among the 1332 patients who visited Happysaem Korean Medicine Clinic between January 1, 2011 and December 31, 2012 with the goal of conceiving. The inclusion criteria were as follows: women aged ≥ 35 years, KHM use of more than 4 weeks, no infertility factor in their male partner, and available follow-up information. Infertility was defined as the inability to conceive for six months or longer after having a normal married life [11]. All patients received KHM treatment from Happysaem Korean Medicine Clinic, although those who received combined western treatments (WT), including ovulation induction (OI), intrauterine insemination (IUI), or IVF at other institutes, were also included (Fig. 1). Finally, the charts of 270 patients were retrospectively evaluated for clinical pregnancy

rates (CPR), live birth rates (LBR), predictors of pregnancy success, and medical costs incurred during the treatment course.

2.2. Treatment

KHM refers to a decoction prescribed individually based on syndrome differentiation according to traditional Korean medicine theory. All patients were instructed to take herbal decoctions three times a day following a meal. Subject who received WT in addition to KHM, mainly used KHM for treatment preparation about 12 weeks before IVF or IUI, and in some cases were provided KHM following embryo transfer to support implantation and protect the fetus. The other combination was medication with ovulation-inducing agents such as clomiphene citrate in addition to KHM without undergoing IVF or IUI. Other traditional Korean medicine treatments such as acupuncture, moxibustion, or cupping were not used. The representative herbal prescriptions were *Chokyungsoyo-san*, *Chokyungonshin-tang*, and *Guichulleekyung-tang*. The herbal remedies we used and detailed compositions of prescriptions are shown in Appendix A.

2.3. Follow-up and assessment

Happysaem Korean Medicine Clinic follows the practice of performing follow-up visits and telephonic follow-up for patients receiving KHM treatment, to check on pregnancy and birth status. Accordingly, patients with verifiable follow-up between 6–12 months after the initial visit were included in the study.

Data related to baseline characteristics including age, duration of infertility, causes and type of infertility, previous ART experience, regularity of menstrual cycle length, and body mass index (BMI) were extracted. The main outcomes were CPR and LBR for the overall study population and for individual groups (KHM treatment only [KHM group] and KHM treatment combined with western treatment [KHM + WT group]). Data on the total medical costs (consultation fee and KHM costs) during the treatment course and the total treatment period was collected and adverse events examined.

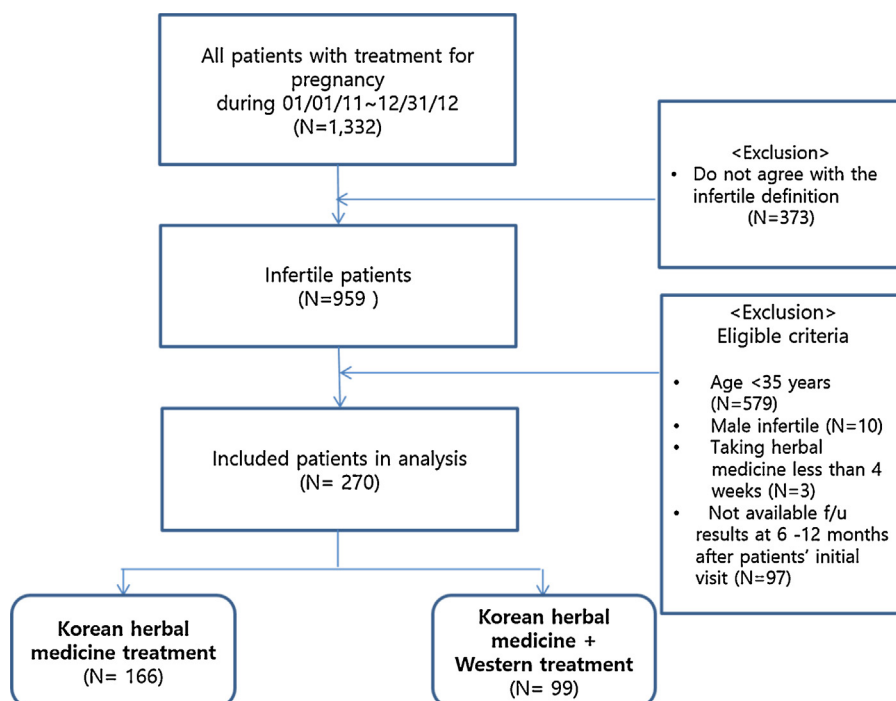


Fig. 1. Flow chart of the analyzed patients.

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