







Characteristics and Outcomes of Herbal Medicine for Female Infertility: A Retrospective Analysis of Data from a Korean Medicine Clinic During 2010–2020

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Purpose: Few studies have assessed outcomes associated with the use of traditional medicine therapies to manage infertility in clinical practice. The aim of this study was to investigate the clinical characteristics of and infertility treatment effects among patients who visited a Korean medicine (KM) clinic to aid in achieving pregnancy. This study consisted of a 10-year analysis of patient records from a KM clinic.

Methods: A retrospective 10-year (2010–2020) chart analysis was performed using the medical records of infertile patients who visited a KM clinic in South Korea for fertility treatment (ICD-10, infertility symptoms: 59 codes).

Results: Of the 6194 patients who visited the clinic during the selected time frame, 1786 were female patients seeking fertility treatment to achieve pregnancy. Among the 1786 infertile women, 586 women succeeded in becoming pregnant (32.8%). Among the 586 patients who became pregnant, 476 women had received KM, 92 had been treated using KM and in vitro fertilization (IVF), and 18 had received KM and undergone intrauterine insemination (IUI). The live birth rates achieved with these treatments were 66.0%, 68.8%, and 66.7%, respectively. The most frequently prescribed medicines were Gamiboher-tang (Jiaweiwuxu-tang), Gamiguibi-tang (Jiaweiguipi-tang), and Gamidanggui-san (Jiaweidanggui-san). Additionally, the most frequent adjunct therapies administered to these patients were acupuncture and moxibustion.

Conclusion: Infertility therapies using KM may be a successful option to treat infertility when used alone or in addition to IVF and IUI. However, further pharmacological investigations and clinical trials are required to ensure the objectivity of the efficacy evaluation.

Keywords: herbal medicine, infertility, pregnancy, pregnancy rate, fertilization in vitro, retrospective studies

Introduction

Various infertility management programs exist worldwide, and assisted reproductive technology (ART) is a key fertility treatment used globally.^{1–3} However, the success rate of ART in the treatment of infertility is only approximately 9–28%.^{1,2} In contrast to the widespread Western application of ART, China, Japan, and South Korea more frequently administer traditional medicine for the treatment of infertility. Approximately 70% of South Korean patients with infertility attempt treatment with Korean medicine (KM) before ART.⁴ In 2012, the government started providing financial support for ART, and such support is frequently made available to infertile couples.

KM, considered a branch of East Asian medicine, is a comprehensive medical system characterized by a unique theoretical basis and practical experience.⁵ KM is an important contributor to the realization of the value of medicine in food, life and culture.⁶ KM includes herbal medicines, acupuncture and other nonpharmacological therapies.⁵⁻⁷

KM for infertility could also improve the overall physical and mental health of women by helping to manage physical conditions as well as emotional imbalances. KM, including herbal medicine, may also increase the blood flow to the cervical mucus and endometrium and promote endometrial stability. This may result in an increased chance of pregnancy, as it creates an optimal environment for conception and addresses not only overall health but also underlying conditions.⁸ KM-based treatment for infertility is considered an alternative therapy with the potential for personalization with multiple therapeutic components. However, clinical trials have tested only the clinical efficacy and safety of single treatments and have ignored the complexities of KM interventions.⁹ A recent multicenter observational study tested the effects of herbal medicines with acupuncture in women with unexplained infertility.¹⁰

A web survey, showed that the most commonly used KM infertility therapy was herbal medicines, whether by themselves or combined with acupuncture (40%) and/or moxibustion (29%).¹¹ The use of herbal medicines for pregnancy-related conditions is prevalent in many countries.¹²⁻¹⁴ Such studies reported that herbal medicines were used to alleviate the discomfort or to improve the success of pregnancy procedures.^{13,14} Recent evidence has shown that herbal medicines may be effective in the treatment of infertility.¹⁵ Since only a handful of studies have evaluated the clinical results of KM infertility therapies,^{10,16} the present study investigated the clinical features and effects of KM therapy on infertility by analyzing the 10-year chart records of patients from a KM clinic.

Methods

Study Design

A retrospective chart review was conducted at a women's KM clinic located in Daejeon, South Korea.

Participants

The outpatient medical records of infertility patients who visited the KM clinic and received KM-based treatment between January 1, 2010, and August 31, 2020, in an attempt to become pregnant were reviewed.

Inclusion and Exclusion Criteria

We included outpatients at the KM clinic for whom infertility symptoms were the main complaint. The outpatient visits were coded according to the 10th revision of the International Classification of Diseases (ICD-10, infertility symptoms: 59 codes). Patients lacking a relevant code for infertility symptoms were excluded from the study.

Variables

- Age, height, body weight, body mass index (BMI), pregnancy success.
- Main female infertility symptoms.
- Commonly prescribed herbal medicines.
- Combined fertility treatment procedures (IVF: in vitro fertilization; IUI: intrauterine insemination) and herbal medicine treatment.
- Major adjunct therapies administered along with herbal medicines (acupuncture, moxibustion, etc.).
- Obstetric outcomes, including the live birth rate.

Data Sources/Measurement

The key sources of data in the present study included case report forms (CRFs) and the electronic medical records (EMRs) of patients obtained from the hospital. Researchers collected patient data (excluding names and personal identification numbers) from the hospital to ensure patient confidentiality.

Statistical Analysis

IBM SPSS Statistics, Version 20.0, Windows (IBM, USA) was used to analyze the findings. Descriptive statistics were used to describe the participant age and herbal medicine prescription frequency distributions.

Results

Basic Characteristics

Out of the 6194 patients who visited a KM women's clinic between 2010 and 2020, 1786 infertility patients were attempting to conceive. Their medical records were analyzed (Figure 1); the mean age was 33.8 years old, and the mean BMI was 21.7. The patients' characteristics are shown in Table 1.

Live Birth Rate

Out of the 1786 infertility patients who visited the KM clinic for infertility treatment, 586 patients successfully achieved pregnancy (32.8%) (Table 1). Out of the 586 pregnant women, 476 had received KM, 92 had been treated with KM and IVF, and 18 had been treated with KM and IUI. The live birth rates achieved with these treatments were 66.0%, 68.8%, and 66.7%, respectively (Table 1).

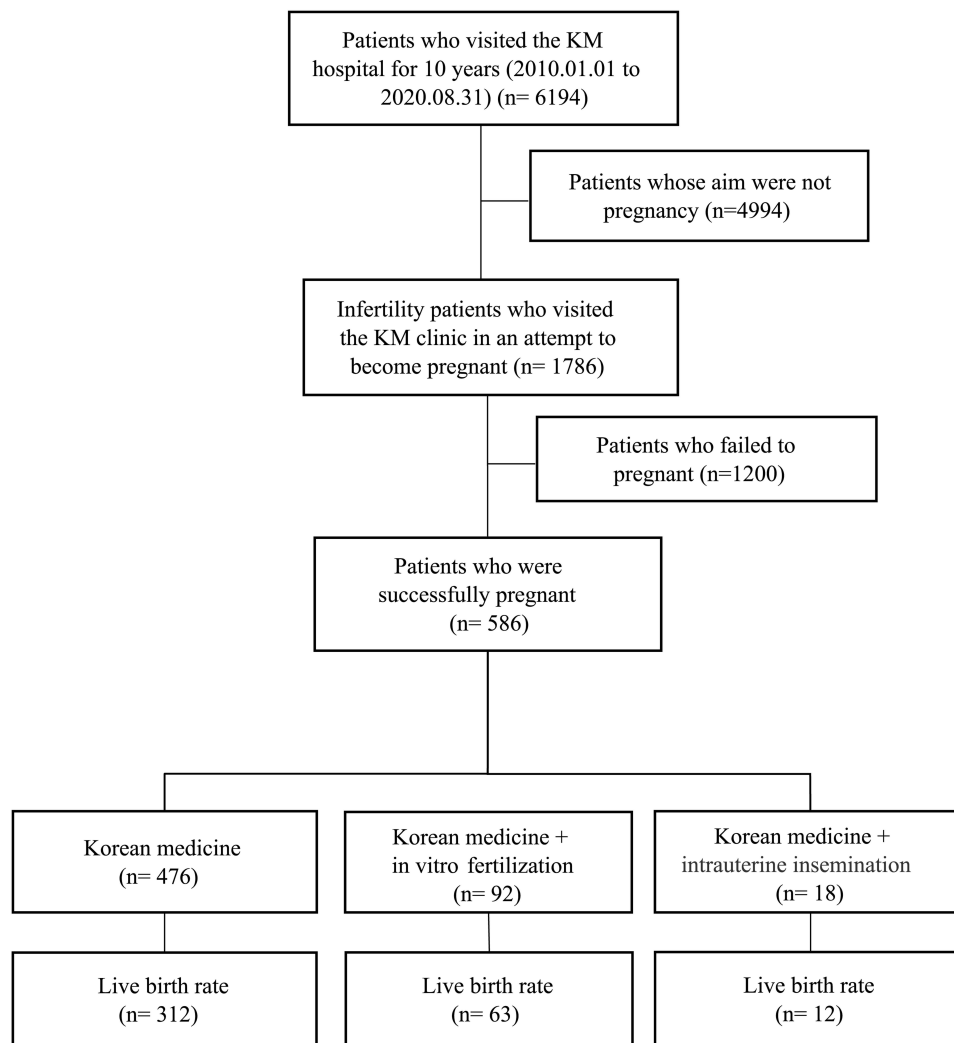


Figure 1 Study flow chart. A flowchart of the patient selection process.

Table 1 Frequency of Pregnancy and Childbirth According to Treatment and Symptoms (n = 1786)

Classification	Total	Pregnancy				Childbirth				Failed to Pregnant
		Subtotal	KM	KM + IVF	KM + IUI	Subtotal	KM	KM + IVF	KM + IUI	
No. of patients	1786	586	476	92	18	387	312	63	12	1200
Age (year)	33.6 (4.65)	32.8 (3.88)	32.6 (3.85)	33.9 (3.70)	34.3 (4.30)	32.6 (3.71)	32.4 (3.67)	33.3 (3.73)	33.8 (3.96)	34.0 (4.94)
Height (cm)	160.7 (5.14)	160.9 (4.94)	160.9 (4.87)	161.2 (5.06)	160.9 (6.12)	161.1 (4.87)	161.0 (4.78)	161.2 (4.96)	161.6 (6.77)	160.6 (5.23)
Weight (kg)	56.2 (9.18)	56.2 (8.94)	56.0 (8.83)	57.6 (9.35)	56.2 (9.66)	56.0 (8.89)	55.9 (9.14)	55.7 (6.93)	58.0 (11.30)	56.2 (9.30)
BMI	21.8 (3.39)	21.7 (3.25)	21.6 (3.23)	22.2 (3.39)	21.7 (3.02)	21.6 (3.24)	21.6 (3.38)	21.4 (2.46)	22.1 (3.34)	21.8 (3.45)

Abbreviations: KM, Korean medical treatments; IVF, in vitro fertilization; IUI, intrauterine insemination.

Infertility Symptoms

[Supplementary 1](#) presents the infertility symptom frequencies among the 1786 patients. Female infertility of a uterine origin was the most frequent symptom, while a cold pattern due to thoroughfare and conception vessel deficiency was the second most frequent symptom. [Supplementary 2](#) shows the frequency of pregnancy and childbirth according to treatments and symptoms.

Main Herbal Medicines and KM Therapies Used to Treat Infertility

Out of the 10 herbal medicines used to treat infertility, the most common prescriptions were Gamiboher-tang (Jiaweiwuxu-tang), Gamiguibi-tang (Jiaweiguipi-tang), and Gamidanggui-san (Jiaweidanggui-san) ([Figure 2A](#)). [Figure 2B](#) list the compositions of the 10 herbal medicines and [Supplementary 3](#) is presented with their Latin name, scientific name and Chinese name. The top 5 KM treatments administered to infertility patients included a combination of acupuncture, moxibustion, cupping, and fumigation ([Supplementary 4](#)).

Discussion

Summary of the Main Results

We analyzed the data of 1786 infertile women who visited the KM clinic to aid in achieving pregnancy over the course of 10 years and found that the pregnancy rate was 32.8% (n=586). The live birth rates were 66.0% and 68.8% in those receiving KM plus IVF and 66.7% in those receiving KM plus IUI, respectively. The most frequently prescribed medicines were Gamiboher-tang (Jiaweiwuxu-tang), Gamiguibi-tang (Jiaweiguipi-tang), and Gamidanggui-san (Jiaweidanggui-san). KM practitioners prescribed acupuncture and moxibustion in addition to herbal medicines for the treatment of infertility.

Agreement and Disagreement with the Results of Other Studies

Recent research has shown the success rate of KM in infertility treatment. One study that investigated the pattern of Chinese herbal medicine usage for infertility showed that the most commonly recommended herbal formulas included Jogyeongjongok-tang (Tiaojing Zhongyu decoction) and Onkyung-tang (Wenjing decoction).¹¹

In another study, the efficacy and safety of KM administered to infertile women participating in 13 KM-based local government infertility programs were assessed.¹⁶ Of the 1023 participants in that study, 887 patients finished the program, of whom 205 reported successful pregnancy (23.1% pregnancy rate). Jogyeongjongok-tang (Tiaojing Zhongyu Tang) was found to be the most frequently administered formula in KM infertility therapies in local governmental programs.

The pregnancy rate results in the current study were similar to those in previous studies.¹⁶ The herbal medicines prescribed to patients in the present study were similar to the most commonly administered medicines for the treatment of female infertility in previous research.^{11,16}

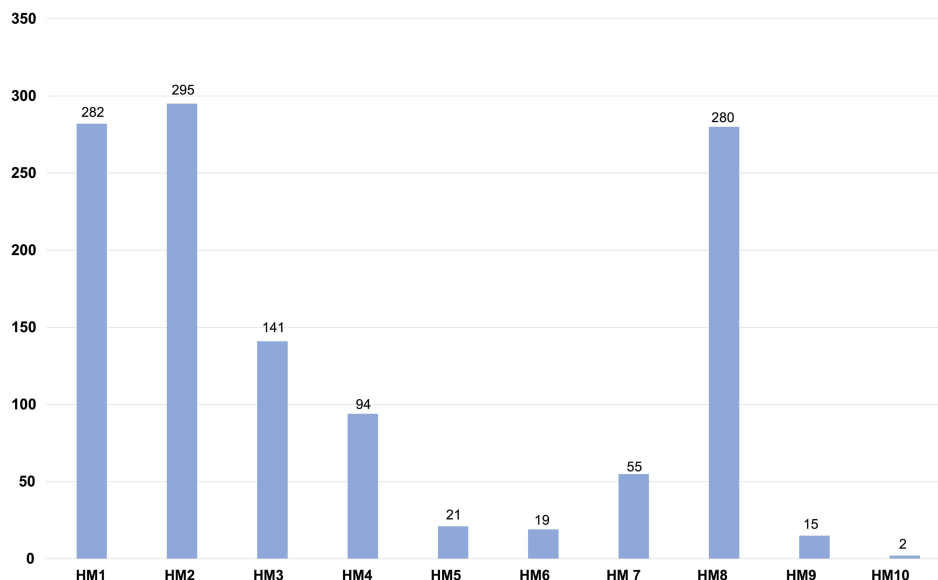
Another study showed that KM herbal medicines enhanced anti-Müllerian hormone levels in infertile women with diminished ovarian reserves.¹⁷ This suggests a potential mechanism of herbal medicine in infertility treatment with KM.

Our analysis showed that acupuncture and moxibustion were used in conjunction with herbal medicines. In clinical practice, combination treatment is very common, as combined treatments can have a synergetic effect on the success of pregnancy.¹⁸ A qualitative study showed that patients who underwent acupuncture for infertility had good outcomes.¹⁹ Recent evidence has shown that acupuncture and moxibustion may improve the success rate of pregnancy when combined with IVF.^{15,20}

Implication for Future Research

The present study suggests that herbal medicines may be beneficial in the treatment of infertility. Considering the popular use of herbal medicines for pregnancy,^{11,13,14,21} further studies are needed to determine their clinical efficacy and safety.²¹ These findings can thus expand the scope of future clinical research on and efficacy evaluations of such therapies.

A Usage frequency of herbal medicines



B The composition of the herbal medicines prescribed for treating infertility patients.

Name of herbal formula (Korean/Chinese)	Composition of herbal formula (Latin compedium name)
HM1: Gamiboher-tang/ Jiaweiwuxu-tang	Spatholobi Caulis 10 g, Astragali Radix 6 g, Ginseng Radix 6 g, Atractylodis Rhizoma Alba 6 g, Angelicae Gigantis Radix 6 g, Cnidii Rhizoma 6 g, Cibotii Rhizoma 6 g, Typhae Pollen 6 g, Trogopterorum Faeces 6 g, Poria Sclerotium 4 g, Citri Unshius Pericarpium 4 g, Glycyrrhizae Radix Preparata 4 g, Persicae Semen 4 g, Carthami Flos 4 g, Corydalis Tuber 4 g, Salviae Miltiorrhizae Radix 4 g, Zingiberis Rhizoma Crudus 3 sliced, Zizyphi Fructus 2 ea
HM2: Gamiguiubi-tang/ Jiaweigui-tang	Astragali Radix Preparata 6 g, Ginseng Radix 6 g, Angelicae Gigantis Radix 6 g, Longan Arillus 6 g, Zizyphi Semen Carbonisatum 6 g, Liriodis seu Ophiopogonis Tuber 6 g, Cnidii Rhizoma 6 g, Paeoniae Radix 6 g, Atractylodis Rhizoma Alba 6 g, Poria Sclerotium Cum Pini Radix 6 g, Poria Sclerotium 6 g, Bupleuri Radix 6 g, Citri Unshius Pericarpium 4 g, Polygalae Radix 4 g, Aucklandiae Radix 2 g, Glycyrrhizae Radix et Rhizoma 2 g, Zingiberis Rhizoma Carbonisatum 2 g, Menthae Herba 2 g, Porcine Placenta 50 g, Zingiberis Rhizoma Crudus 5 sliced, Zizyphi Fructus 2 ea
HM3: Gamidaeyoung-jeon/ Jiaweidaying-jian	Rehmanniae Radix Preparata 20 g, Angelicae Gigantis Radix 12 g, Spatholobi Caulis 12 g, Cyperi Rhizoma Carbonisatum 8 g, Zizyphi Semen Carbonisatum 8 g, Lycii Fructus 8 g, Eucommiae Cortex 8 g, Ginseng Radix 6 g, Atractylodis Rhizoma Alba 6 g, Paeoniae Radix 6 g, Poria Sclerotium Cum Pini Radix 6 g, Achyranthis Radix 6 g, Citri Unshius Pericarpium 4 g, Cinnamomi Cortex 4 g, Glycyrrhizae Radix et Rhizoma 4 g, Salviae Miltiorrhizae Radix 4 g, Carthami Flos 2 g, Polygalae Radix 2 g, Porcine Placenta 50 g
HM4: Gamitaeuonem/ Jiaweitaiyuan-yin	Rehmanniae Radix Preparata 12 g, Ginseng Radix 8 g, Angelicae Gigantis Radix 8 g, Paeoniae Radix 8 g, Lycii Fructus 8 g, Eucommiae Cortex 8 g, Astragali Radix 6 g, Atractylodis Rhizoma Alba 6 g, Dipsaci Radix 6 g, Anisi Corii Colla 6 g, Citri Unshius Pericarpium 4 g, Glycyrrhizae Radix Preparata 4 g, Porcine Placenta 50 g
HM5: Gamibosaengtang/ Jiaweibusheng-tang	Longan Arillus 12 g, Atractylodis Rhizoma Alba 8 g, Cyperi Rhizoma 8 g, Linderiae Radix 8 g, Citri Unshius Pericarpium 8 g, Eriobotryae Folium 8 g, Ginseng Radix 4 g, Poria Sclerotium 4 g, Glycyrrhizae Radix et Rhizoma 4 g, Amomi Fructus Rotundus 4 g, Amomi Fructus 4 g, Aucklandiae Radix 4 g, Phyllostachyos Caulis in Taeniam 4 g, Perillae Folium 2 g, Alpiniae Oxyphyllae Fructus 2 g, Zingiberis Rhizoma Crudus 5 sliced
HM6: Gamigungso-san/ Jiaweiqionsu-san	Bupleuri Radix 6 g, Scutellariae Radix 6 g, Peucedani Radix 6 g, Liriodis seu Ophiopogonis Tuber 6 g, Cnidii Rhizoma 4 g, Citri Unshius Pericarpium 4 g, Paeoniae Radix 4 g, Atractylodis Rhizoma Alba 4 g, Cyperi Rhizoma 4 g, Amomi Fructus 4 g, Perillae Folium 3 g, Puerariae Radix 3 g, Schisandrae Fructus 3 g, Glycyrrhizae Radix et Rhizoma 2 g, Zingiberis Rhizoma Crudus 3 sliced, Allii Fistulosi Bulbus 3 sliced
HM7: GamiKyoaesamul-tang/ Jiaweiijaouisuwu-tang	Anisi Corii Colla 8 g, Artemisiae Argyi Herba (Carbonisatum) 8 g, Sanguisorbae Radix Carbonisatum 8 g, Angelicae Gigantis Radix 8 g, Cnidii Rhizoma 8 g, Rehmanniae Radix Preparata 4 g, Paeoniae Radix 4 g, Scutellariae Radix 4 g, Atractylodis Rhizoma Alba 4 g, Amomi Fructus 4 g, Cyperi Rhizoma (Preparata) 4 g, Schizonepetae Spica Carbonisatum 4 g, Thujae Orientalis Folium (Carbonisatum) 4 g, Oryzae Semen 2 g
HM8: Gamidanggui-san/ Jiaweidanggui-san	Astragali Radix 8 g, Atractylodis Rhizoma Alba 8 g, Angelicae Gigantis Radix 6 g, Cnidii Rhizoma 6 g, Paeoniae Radix 6 g, Scutellariae Radix 6 g, Rehmanniae Radix Preparata 4 g, Ginseng Radix 4 g, Poria Sclerotium 4 g, Citri Unshius Pericarpium 4 g, Amomi Fructus 4 g, Glycyrrhizae Radix et Rhizoma 4 g, Perillae Folium 3 g, Cimicifugae Rhizoma 2 g
HM9: Gamicugtaeeum/ Jiaweisuotai-yin	Arecae Pericarpium Preparata 8 g, Glycyrrhizae Radix Preparata 6 g, Angelicae Gigantis Radix 4 g, Atractylodis Rhizoma Alba 4 g, Paeoniae Radix 4 g, Cnidii Rhizoma 2 g, Ginseng Radix 2 g, Citri Unshius Pericarpium 2 g, Perillae Folium 2 g, Aurantii Fructus Immaturus 2 g, Amomi Fructus 2 g
HM10: Gaminangan-jeon/ Jiaweinuangan-jian	Spatholobi Caulis 12 g, Lycii Fructus 12 g, Angelicae Gigantis Radix 8 g, Poria Sclerotium 8 g, Linderiae Radix 8 g, Foeniculi Fructus 8 g, Cinnamomi Cortex 4 g, Aucklandiae Radix 4 g, Salviae Miltiorrhizae Radix 4 g, Carthami Flos 2 g, Zingiberis Rhizoma Carbonisatum 2 g

Figure 2 (A) Usage frequency and (B) the composition of the herbal medicines prescribed for treating infertility patients.

Limitations

In the present study, an analysis of the clinical data of 1786 infertility patients among a total of 6194 patients was conducted; the data were collected from a KM women's clinic in South Korea. However, even though the aim was to study the effects of KM on infertility in women, this retrospective study was limited by the lack of a comparison group, the lack of control of confounders and the single-clinic setting. Additionally, there was a lack of additional information on the origin of infertility, additional information about unsuccessful pregnancies and fetal death and an eligible patient pool that could provide objective information on KM in future research. Furthermore, the focus of the current study was limited to herbal prescriptions alone and did not evaluate each herb individually. Last, since the present study was performed using case files/ patient records, monitoring outcomes related to the improvement in symptoms was not possible.

Conclusion

Three major infertility herbal prescriptions, namely, Gamiboher-tang (Jiaweiwuxu-tang), Gamiguibi-tang (Jiaweiguipi-tang), and Gamidanggui-san (Jiaweidanggui-san), are primarily prescribed, and the pregnancy rate after treatment with these prescriptions is 32.8%. Based on the results and limitations of the present study, further well-designed clinical trials must be conducted to further establish the efficacy of these treatments and construct a database of effective herbal prescriptions.

Data Sharing Statement

Data will be made available upon reasonable request.

Ethics Approval

This study was conducted in accordance with the principles of the Declaration of Helsinki and approval by the Institutional Review Board (IRB) of the Korea Institute of Oriental Medicine (I-2002/002-006). Personal private information was deleted in advance, and statistical analyses were conducted with strict confidentiality and only used for scientific purposes. Signed informed consent forms were waived by the Institutional Review Board of the Korea Institute of Oriental Medicine.

Author Contributions

All authors (E.K., H.W.L., N.K., Y.H.P., T.-Y.C., and M.S.L) made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors report no conflicts of interest in this work.

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