

## Heyan Kuntai capsule versus dehydroepiandrosterone in treating Chinese patients with infertility caused by diminished ovarian reserve: a multicenter, randomized controlled trial

Gao Hui, Xia Tian, Ma Ruihong, Zhao Zhimei, Song Xueru, Wang Baojuan, Liu Lijing, Han Kaimei, Wang Guoqing, Fu Yu, Hao Guimin

**Gao Hui**, Department of Traditional Chinese Medicine, Affiliated Hospital of Chengde Medical College, Chengde 067000, China

**Xia Tian, Ma Ruihong, Zhao Zhimei, Wang Baojuan**, Department of Reproductive Center, First Teaching Hospital of Tianjin University of Traditional Chinese Medicine, Tianjin 300193, China

**Song Xueru**, Department of Reproductive center, Tianjin Medical University General Hospital, Tianjin 300052, China

**Liu Lijing, Han Kaimei, Wang Guoqing**, Graduate School, Tianjin University of Traditional Chinese Medicine, Tianjin 300193, China

**Fu Yu**, Department of Acupuncture, First Teaching Hospital of Tianjin University of TCM, Tianjin 300193, China

**Hao Guimin**, Department of Reproductive Center, The Second Hospital of Hebei Medical University, Shijiazhuang 050000, China

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**Correspondence to:** Xia Tian, Department of Reproductive center, First Teaching Hospital of Tianjin University of TCM, Tianjin 300193, China. Email: [xiatian76@163.com](mailto:xiatian76@163.com)

**Telephone:** +86-22-27987335

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### Abstract

**OBJECTIVE:** To evaluate the clinical efficacy and safety of Heyan Kuntai capsule (HYKT) in treating women with infertility caused by diminished ovarian reserve (DOR).

**METHODS:** One hundred eight eligible patients

from three Chinese hospitals were randomly divided into an HYKT treatment group ( $n = 55$ ) or a dehydroepiandrosterone (DHEA) treatment group ( $n = 53$ ). Patients in the HYKT group were treated orally with four 0.5 g HYKT three times a day; patients in the DHEA group were treated with one 25.0 mg DHEA capsule three times a day. All patients were treated for 3 months and followed up over a 3-month period.

**RESULTS:** Of 108 patients, 12 dropped out: six from the HYKT group, and six from the DHEA group. Eleven patients got pregnant during the treatment. Serum anti-Müllerian hormone levels and antral follicle counts increased significantly in both groups after treatment ( $P < 0.05$ ) especially in the HYKT group ( $P < 0.05$ ). Serum follicle stimulating hormone (FSH) levels and FSH/luteinizing hormone ratios decreased ( $P < 0.05$ ) with no significant difference between the two groups. Estradiol levels in the HYKT group and DHEA-sulfate levels in the DHEA group both increased ( $P < 0.05$ ). The spontaneous pregnancy rates were 12% and 11% in the HYKT and DHEA groups, respectively (not significant). During the follow-up period, 16 patients in the HYKT group underwent *in vitro* fertilization-embryo transfer (IVF-ET) and the number of retrieved oocytes was  $(5.1 \pm 1.8)$ . In DHEA group, 20 patients underwent IVF-ET and the number of retrieved oocyte was  $(4.2 \pm 1.9)$  (not significant); clinical pregnancy rates were 38% in the HYKT group and 20% in DHEA group (not significant). No significant adverse reactions were observed.

**CONCLUSION:** HYKT can improve the ovarian re-

serve and hormone levels in patients with infertility caused by DOR. Pregnancy rates after HYKT treatment were similar to those of DHEA treatment. HYKT might be an alternative to the treatment of infertility caused by DOR.

**Keywords:** Infertility, female; Ovarian reserve; Hormones; Dehydroepiandrosterone; Heyan Kuntai capsule; Randomized controlled trial

## INTRODUCTION

The concept of ovarian reserve (OR) describes female reproductive potential as a function of the number and quality of oocytes. Good OR is responsible for producing high-quality oocytes and successful pregnancy. Diminished or decreased ovarian reserve (DOR) indicates that some women of childbearing age have normal menstrual cycles, but that their ovarian stimulation response or fertility is lower than that in other women of the same age.<sup>1</sup> There are many factors that affect OR, such as age, endometriosis, living conditions, ovarian surgery, heredity and mutation, immune system defects, radiation, and chemotherapy, each of which could directly or indirectly result in a decline in a woman's oocyte quantity and quality.<sup>2</sup>

The greatest harm of DOR to women is fertility loss or complete infertility. In 2011, 26.0% of the American infertility patients who used assisted reproductive technology (ART) were diagnosed with DOR.<sup>3</sup> In 2013, the American Centers for Disease Control ART Success Report stated that DOR was the second most common reason (32.0%) that a family experiencing infertility underwent ART treatment, second only to male-factor infertility (33.0%).<sup>4</sup> Although ART has developed rapidly in recent years, the low clinical pregnancy and low live birth rates for patients with DOR are becoming a bottleneck that limits its further development.<sup>5</sup> Finding methods by which the present treatments for DOR can be improved has aroused concerns among reproductive specialists worldwide.

The conventional treatments for DOR focus mainly on increasing gonadotropin levels to stimulate ovulation and the growth hormones used during in vitro fertilization-embryo transfer (IVF-ET); however, their clinical efficacy lacks a unified understanding. Some studies have suggested that dehydroepiandrosterone (DHEA) supplements before and during IVF might improve ovarian reserve.<sup>6,7</sup> These studies mainly demonstrated that, with DHEA treatment, the oocyte and embryo quantity and quality were enhanced,<sup>8,9</sup> pregnancy outcomes improved,<sup>10</sup> spontaneous abortion rates were reduced,<sup>11</sup> and embryonic aneuploidy rates were reduced.<sup>12</sup> An online survey in 2010 revealed that 25.8%

of worldwide IVF centers would treat patients with DOR using DHEA supplementation;<sup>13</sup> however, because of the weak androgenic characteristic of DHEA, the safety of long-term use needs further investigation. Infertility caused by DOR has been treated with Traditional Chinese Medicine (TCM) in China for several thousand years. The Chinese patented medicine Heyan Kuntai capsule (HYKT) originates from a Huang Lian E Jiao decoction recorded in the *Shang Han Lun*. The formula is mainly composed of prepared Dihuang (*Radix Rehmanniae*), Huanglian (*Rhizoma Coptidis*), Baishao (*Radix Paeoniae Alba*), Huangqin (*Radix Scutellariae Baicalensis*), Ejiao (*Colla Corii Asini*), Fuling (*Poria*). It has the effect of nourishing *Yin* and clearing heat, tranquilizing the mind, and eliminating vexation. It was confirmed that HYKT could effectively improve endometrium receptivity in patients with infertility,<sup>14,15</sup> increase retrieved oocyte numbers in patients with DOR, improve the quality of oocytes and embryos,<sup>16</sup> and improve the pregnancy rate among such patients. Based on the above studies, we aimed to investigate the clinical efficacy and safety of HYKT on infertility in patients with DOR.

## MATERIALS AND METHODS

This multicenter, randomized controlled study was conducted on outpatients of the First Teaching Hospital of Tianjin University of Traditional Chinese Medicine, the Fertility Center of Tianjin Medical University General Hospital, and the Fertility Center of the Second Hospital of Hebei Medical University from November 2013 to December 2014. All procedures were in accordance with the Helsinki Declaration on Human Experimentation and approved by the Ethics Committee of the First Teaching Hospital of Tianjin University of Traditional Chinese Medicine (approval No. TYLL2013[K]010; clinical trial registration number ChiCTR-TRC-13004085 [http:Ur

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