

ORIGINAL

Effectiveness of chromic catgut implantation in men with idiopathic infertility

Efectividad de la implantación de catgut crómico en hombres con infertilidad idiopática

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ABSTRACT

Introduction: the treatment of idiopathic male infertility is empirical and controversial.

Objective: to assess the effectiveness of chromic catgut implantation at selected acupuncture points according to traditional Chinese syndromic diagnosis in men with idiopathic infertility.

Methods: quasi-experimental study with pre-test-post-test and control group, in 135 patients with idiopathic infertility divided into: study group (67 treated with catgut implantation) and control group (68 treated with medication). A traditional medical history was taken and descriptive and inferential statistics were used.

Results: mean age was similar in both groups ($33,90 \pm 6,28$ years study group and $33,68 \pm 5,6$ years control group). Patients with Kidney yang vacuum predominated (55,2 % study group and 52,9 % control group). Both groups showed highly significant differences in sperm concentration, motility and morphology before and after treatments and between groups. Clinical improvement (64,2 % vs. 8,8 %), spermogram normalisation (53,7 % vs. 16,2 %) and pregnancy achievement (17,9 % vs. 4,4 %) were higher in patients treated with chromic catgut implantation compared to those using Clomiphene.

Conclusions: chromic catgut implantation in selected acupuncture points according to traditional Chinese syndromic diagnosis in men with idiopathic infertility is effective because it improves sperm concentration, motility and morphology, normalises the spermogram and contributes to achieving pregnancies with increased fertility, to a greater extent than treatment with Clomiphene; together with the clinical improvement of the patients.

Keywords: Infertility; Idiopathic Oligoasthenoteratozoospermia; Catgut Implantation.

RESUMEN

Introducción: el tratamiento de la infertilidad masculina idiopática es empírico y controversial.

Objetivo: valorar la efectividad de la implantación de catgut crómico en puntos de acupuntura seleccionados según diagnóstico sindrómico tradicional chino, en hombres con infertilidad idiopática.

Métodos: estudio cuasiexperimental con preprueba-posprueba y grupo de control, en 135 pacientes con infertilidad idiopática divididos en: grupo estudio (67 tratados con implantación de catgut) y grupo control (68 tratados con medicamentos). Se llenó historia clínica tradicional y se utilizó estadística descriptiva e inferencial.

Resultados: La media de la edad fue similar en ambos grupos ($33,90 \pm 6,28$ años grupo estudio y $33,68 \pm 5,6$ años grupo control). Predominaron los pacientes con vacío de yang de Riñón (55,2 % grupo estudio y 52,9 % grupo control). Ambos grupos mostraron diferencias muy significativas en cuanto a concentración, motilidad y morfología espermática antes y después de los tratamientos y entre los grupos. La mejoría clínica (64,2 % Vs 8,8 %), normalización del espermograma (53,7 Vs 16,2 %) y logro de embarazo (17,9 % Vs 4,4 %) fue superior en los pacientes tratados con implantación de catgut crómico respecto a los que usaron Clomifeno.

Conclusiones: la implantación de catgut crómico en puntos de acupuntura seleccionados según diagnóstico sindrómico tradicional chino en hombres con infertilidad idiopática, es efectiva porque mejora la concentración, motilidad y morfología espermática, normaliza el espermograma y contribuye al logro de embarazos con aumento de la fecundidad, en mayor medida que el tratamiento con Clomifeno; unido a la mejoría clínica de los pacientes.

Palabras claves: Infertilidad; Oligoastenoteratozoospermia Idiopática; Implantación de Catgut.

INTRODUCTION

According to estimates by the World Health Organization in the year 2020, infertility affects up to 15 % of couples of reproductive age worldwide.^(1,2) Babakhanzadeh E et al. and Choy JT et al. indicate that about half of the cases of infertility occur due to female factors, 20 to 30 % due to male factors, and 20 to 30 % due to causes common to both sexes.^(3,4)

However, Agarwal et al. state that the distribution of this disease due to the male factor ranges from 20 % to 70 % and that at least 30 million men worldwide are infertile.⁽⁵⁾

In Cuba, Álvarez RT et al., in the year 2021, state that "the most recognized studies so far are the research carried out and published 30 years ago by Dr. Padrón Durán and other collaborators, in which a prevalence of infertility between 12 and 14 % was reported, a behavior very similar to the international one".⁽⁶⁾

Studies carried out on infertility in Pinar del Río, Valladares M, in 2003, and Fernández H, in 2013 coincide in stating that the female cause is predominant and report an increase of the male factor due to idiopathic alterations of semen quality.^(7,8)

The precise etiology of male factor infertility remains undefined in 30 to 50 % of patients classified as idiopathic male infertility.⁽⁹⁾ In these patients, the physical examination and the results of endocrine, genetic, and biochemical studies are normal.⁽¹⁰⁾

Idiopathic alterations of semen quality are defined as unexplained decreases in sperm concentration, motility, and morphology. It can appear alone or in combination (oligo- and astheno- and teratozoospermia and azoospermia).⁽¹¹⁾

The treatment of these alterations is empirical. Agarwal et al. claim that the scientific evidence about the treatments used is limited due to the absence of large clinical trials.⁽⁹⁾ Chehab M et al. report that the systematic reviews and meta-analyses evaluating the effectiveness of treatments have inconclusive results.⁽¹²⁾

Acupuncture and modalities of this technique are applied alone or in combination in the alterations of semen quality with positive results published in international articles.^(13,14,15,16,17,18) It improves the flow of qi, eliminates obstructions, and harmonizes the organs (mainly the kidney, spleen, and liver). From Western medicine, it stimulates the nervous system, regulates blood flow and hormone release, and strengthens the immune system.^(19,20)

The implantation of chromic catgut or seeding is a variant of acupuncture with the same mechanism of action as acupuncture; it is more advantageous because it exerts continuous and prolonged stimulation for approximately 30 days, has stronger long-term effects, reduces cost and time of treatment, and improves compliance by the patient who comes for consultation only once a month.^(21,22,23)

The worldwide increase of couple infertility, with high participation of the malefactor and increase of idiopathic alterations of semen quality and the experiences of the author, who has been researching the subject for more than 10 years with published results^(24,25,26) justifies this research which aims to assess the effectiveness of chromic catgut implantation in selected acupuncture points according to traditional Chinese syndromic diagnosis, in men with idiopathic infertility.

METHODS

A quasi-experimental study with pre-test-post-test and control group was carried out in the Department of Natural and Traditional Medicine of the General Teaching Hospital "Abel Santamaría Cuadrado" of Pinar del Río, Cuba, in the period January 2015-January 2017. The universe was constituted by men who attended the Provincial Center for Assisted Reproduction and were diagnosed by the urologist with idiopathic infertility, who met the selection criteria.

The sample consisted of 135 patients: 67 in the study group (implantation of catgut in acupuncture points selected according to traditional Chinese diagnosis every 28 days for six months) and 68 in the control group (treatment with Clomiphene 50mg one tablet daily for six months).

In the first consultation, the data of all patients were collected using traditional clinical history, where the programs performed during the study were included. Clinical evaluation and program analysis were performed on all patients before starting the corresponding treatment, and every three months, the data from the final

evaluation (six months) were taken for the research.

Some of the variables studied were age, diagnosis by Zang-Fu organs, clinical improvement, seminal characteristics, normalization of the program, and achievement of pregnancies. Statistical methods were used to analyze the behavior of the variables; the Kolmogorov-Smirnov test was used to verify the distribution of the variables. The Student's t-test, Wilcoxon signed-rank test for related samples, Mann Whitney U for independent samples, absolute and relative frequencies for qualitative variables, and the Chi-square test for independence were used. A statistical significance level of five percent ($p < 0,05$) was considered.

The study was conducted in accordance with the ethical principles for human medical research, which were established in the Declaration of Helsinki. Before inclusion in the study, each patient was asked for informed consent. The research was submitted for consideration and approved by the institutional Scientific and Ethics Council, as well as the Provincial Scientific Council. The project received the endorsement of the Cuban Academy of Sciences (ACC), which is affiliated with the Ministry of Science, Technology and Environment (CITMA).

RESULTS

The mean age was similar in both groups ($33,90 \pm 6,28$ years for the study group and $33,68 \pm 5,6$ years for the control group), with no significant differences ($p = 0,831$; Student's t-test for independent samples).

The differentiation of the syndromes, according to Traditional Chinese Medicine, is made from the exhaustive analysis of all the symptoms and signs, the observation of the tongue, and the palpation of the pulse. In most of the patients (55,2 % study group and 52,9 % control group), there was evidence of Kidney yang deficiency; 22,4 % of the study group and 23,5 % of the control group had Kidney yin deficiency; and 9,0 % (study group) and 13,2 % (control group) had Kidney jing deficiency (table 1).

The complex or combined syndromes diagnosed were Spleen and Kidney yang deficiency and Liver and Kidney yin deficiency.

Table 1. Diagnosis by Zang-Fu organs according to groups				
Organ-based diagnostics Zang-Fu	Study group (n=67)		Control group (n=68)	
	#	%	#	%
Kidney yang vacuum	37	55,2	36	52,9
Kidney yin deficiency	15	22,4	16	23,5
Kidney jing insufficiency	6	9,0	9	13,2
Spleen and Kidney yang depletion	6	9,0	4	5,9
Liver and Kidney yin depletion	3	4,5	3	4,4
Total	67	100	68	100
Source: traditional medical records				

Table 2 shows the clinical improvement of men with infertility who received treatment with chromic catgut implantation (64,2 %), evidenced by the positive modification of more than 50 % of the symptoms and signs collected at the beginning of the study and of the tongue and pulse. In the case of patients who received drug treatment, clinical improvement occurred in 8,8 %. The Chi-square test ($X^2 = 44,73$; $p < 0,001$) showed a significant association between clinical improvement and chromic catgut implantation.

Table 2. Clinical improvement according to groups					
Clinical improvement	Study group (n=67)		Control group (n=68)		p*
	#	%	#	%	
Si	43	64,2	6	8,8	<0,001
No	24	35,8	62	91,2	
Source: traditional clinical history					
*Chi-square test (X ²). Relative Risk (RR): 3.15 CI-95 %: 2.20-4.49					

To assess the effectiveness of the proposed treatment, the seminal characteristics of patients with idiopathic infertility before and after catgut implantation or drug treatment were compared. Both groups showed highly

significant differences ($p < 0,001$) between the two times evaluated (before and after) in terms of sperm concentration (table 3), sperm motility (table 4), and sperm morphology (table 5).

Table 3. Sperm concentration by group			
Time	Statistician	Study group (n=67)	Control group (n=68)
Before	Median (IQR)*	12(6)	12 (5)
	Minimum	5	3
	Maximum	19	19
	p**	0,061	
After	Median (IQR)*	26 (14)	15 (10)
	Median (IQR)*		
	Minimum	5	3
	Maximum	52	35
	p**	<0,001	
p***		<0,001	<0,001
Source: traditional medical records			
*IQR: interquartile range, ** Mann-Whitney U-test for independent samples, *** Wilcoxon signed rank test			
Sperm concentration (106/ml)			

Table 4. Sperm motility according to groups			
Time	Statistician	Study group (n=67)	Control group (n=68)
Before	Median (IQR)*	10 (5)	10 (5)
	Minimum	0	0
	Maximum	24	20
	p**	0,895	
After	Median (IQR)*	25 (10)	10 (7)
	Median (IQR)*		
	Minimum	0	0
	Maximum	50	35
	p**	<0,001	
p***		<0,001	<0,001
Source: traditional medical records			
*IQR: interquartile range, ** Mann-Whitney U test for independent samples, *** Wilcoxon signed-rank test			
Sperm motility (%)			

Table 5. Sperm morphology according to groups			
Time	Statistician	Study group (n=67)	Control group (n=68)
Before	Median (IQR)*	10 (5)	10 (5)
	Minimum	5	0
	Maximum	24	25
	p**	0,783	
After	Median (IQR)*	25 (10)	10 (5)
	Median (IQR)*		
	Minimum	0	0
	Maximum	50	35
	p**	<0,001	

p***	<0,001	<0,001
Source: traditional medical records		
*IQR: interquartile range, ** Mann-Whitney U-test for independent samples, *** Wilcoxon signed rank test		
Sperm morphology (%)		

The percentage of men with idiopathic infertility who normalized spermograms was higher in the study group (53,7 %) compared to the control group (16,2 %). The chi-square test ($X^2= 20,97$; $p<0,001$) showed a significant association between spermogram normalization and catgut implantation. The probability of spermogram normalization is 2,17 times higher in patients with chronic catgut implantation (CI-95 % greater than 1; 1,57-3,01). (table 6).

The number of pregnancies achieved after treatment with catgut implantation was higher (17,9 %) compared to those recorded after drug treatment (4,4 %). The chi-square test ($X^2= 6,23$; $p=0,013$) showed a significant association between pregnancy achievement and chronic catgut implantation. The probability of achieving pregnancy is 1,75 times higher in patients with chronic catgut implantation (CI-95 % greater than 1; 1,27-2,40). (table 6).

Table 6. Normalization of spermogram and pregnancy achievement according to groups					
Normalization of spermogram	Study group (n=67)		Control group (n=68)		p*
	#	%	#	%	
Yes	36	53,7	11	16,2	<0,001
No	31	46,3	57	83,8	
Pregnancy achieved					
Yes	12	17,9	3	4,4	0,013
No	55	82,1	65	95,6	
Source: traditional clinical history					
*Chi-square test (X ²), Relative Risk (RR): 2,17 CI-95 %: 1,57-3,01					
*Chi-square test (X ²), Relative Risk (RR): 1,75 CI-95 %: 1,27-2,40					

DISCUSSION

According to the theories of Traditional Chinese Medicine, the syndrome is known as a "pattern" and has served as a key concept and theoretical summary of symptom profiles for diagnosis and treatment of diseases.⁽²⁷⁾ The empty or deficiency of Kidney yang and empty or deficiency of Kidney yin syndromes predominated in the patients of the sample. It coincided with those who had clinical improvement, normalization of the program, and achievement of pregnancy of the couple. This association is related to the involvement of the Kidney organ in a unique way.

In Traditional Chinese Medicine, the Kidney stores the essence and governs growth, development, and reproduction.⁽²⁸⁾ Trying to establish a relationship with Western Medicine, it has been interpreted as part of the endocrine activity of the sexual organs, testicles, and ovaries, as well as the activity of the adrenal and thyroid glands.⁽²⁹⁾

Kidney yang vacuum syndrome is one of the classic syndrome patterns in this medicine and is characterized by disorders of multiple metabolic pathways. Modern research has indicated that functional disorders and damage to the hypothalamic-pituitary-adrenal axis are the major pathological mechanisms underlying this syndrome.⁽³⁰⁾

Zheng P et al. analyzed the mechanism of this syndrome in 67 infertile men and investigated changes in plasma metabolites and metabolic pathways. Coincident with the results, they identified the metabolic profiles of infertile men with Kidney yang vacuum, distinguishing them from healthy controls. They reported 10 biomarkers and 6 metabolic pathways, suggesting that oligozoospermia may be closely associated with energy consumption and antioxidant defenses in spermatogenesis, with energy disorders and amino acid metabolisms being relevant in this syndrome.⁽³¹⁾

In a recent study by Zhang Z and collaborators, this topic is addressed where 813 infertile men were investigated, evidencing basic syndromes of Kidney yang deficiency, followed by Kidney qi deficiency, Spleen yang deficiency, and Liver qi stagnation, among others. In this report, references are made to other authors who have also found kidney yang deficiency to be the main syndrome.⁽²⁰⁾

Studies carried out by other authors^(15,16,17,32,33,34,35) using acupuncture and its variants in the treatment of

male infertility agree with the results obtained with catgut implantation in the positive modification of seminal characteristics (concentration, mobility, and morphology) and the achievement of pregnancies.

In comparison with acupuncture, catgut takes several days to be absorbed, generally between three and four weeks, which allows for a continuous and prolonged stimulus that harmonizes yin and yang, balances the functions of the Zang-Fu organs, unblocks meridians and collaterals, regulates qi and blood, tonifies deficiency and eliminates excess, strengthens anti-pathogenic qi and dissipates pathogenic factors.^(36,37)

From the perspective of Western medicine, it improves nerve functions, enhances immune function and local microcirculation, inhibits the production of inflammatory factors, regulates the neuroendocrine-immune network, reduces cell apoptosis, and regulates cytokines to accelerate metabolism.^(36,37)

In addition, patients will accept the method; the fact that it is done only once a month makes it convenient since it avoids a large number of visits to the office, in addition to perceiving a more effective and prolonged effect.

Siterman et al. report a study with patients similar to those treated but with the use of acupuncture in one group, which they compare with another group without acupuncture treatment. In this case, they also showed significant improvement in sperm motility and morphology in men where acupuncture was used in comparison with the control group.⁽³²⁾

This author, in another study, where he uses selected points according to traditional diagnosis, including the empty syndrome of Kidney yang, shows an increase in sperm count after acupuncture in men with asthenozoospermia and sperm production in azoospermic men.⁽³³⁾

Subsequently, these researchers ratify the positive influence of acupuncture treatment on sperm production, in this case, by decreasing scrotal temperature. In the study, points related to Kidney deficiency syndromes are used. Unlike the present research, it also diagnoses humidity-heat syndromes in concordance with hyperthermia and inflammation of the genital tract.⁽¹⁶⁾

Pei J et al., in agreement with the present investigation, in a study of 40 men with oligozoospermia, asthenozoospermia, or idiopathic teratozoospermia, of whom 28 received acupuncture, report a statistically significant increase in the number of spermatozoa without ultrastructural defects, compared to patients in the control group who did not receive acupuncture treatment. In addition, the authors confirm a significant increase in progressive motility, which correlates with improved sperm morphology.⁽¹⁵⁾

Dieterle et al. report coincident results in a clinical trial where men with severe oligoasthenozoospermia are randomly divided into two treatment groups: acupuncture (24 patients) and placebo acupuncture (28 patients). A significant increase in sperm motility is reported in the patients who received acupuncture.⁽¹⁷⁾

Zhang M et al. studied 22 patients with idiopathic semen disorders and showed significant increases three months after acupuncture in rapid progressive motility and normal sperm ratio.⁽³⁴⁾ Bidouee F et al. also agree with the present study in terms of syndromes diagnosed and points used when acupuncture was applied in a patient with unobstructed azoospermia, where an increase in sperm concentration and motility was reported after treatment.⁽³⁵⁾

The use of chromic catgut implantation in the treatment of alterations of sperm parameters, in the bibliography consulted by the author, is only reported in a study by the Cuban authors Chaviano M et al., who performed sowing in the Sanyinjiao point (Spleen 6) in men with oligozoospermia who do not improve with conventional treatment. In contrast to the present investigation, no traditional Chinese syndromic diagnosis is made, and a single point is used. They agree in confirming satisfactory results in more than 60 % of patients, most of them with mild and moderate oligozoospermia.⁽³⁸⁾

There is no standard reference treatment in the approach to idiopathic male infertility. Treatment of this disease is empirical. The effectiveness of chromic catgut implantation in acupuncture points according to traditional Chinese syndromic diagnosis was compared with that of Clomiphene, which is one of the drugs frequently used in this condition.

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CONFLICT OF INTEREST

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