



## ORIGINAL ARTICLES

### Effectiveness of catgut implantation in patients with moderate and severe persistent bronchial asthma

### Utilidad de la implantación de catgut en pacientes con asma bronquial persistente moderada y severa

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**Received:** January 22 2019

**Accepted:** March 27 2019

**Published:** May 1 2019

**Citar como:** Ramos García IY, Zamora Méndez ED. Utilidad de la implantación de catgut en pacientes con asma bronquial persistente moderada y severa. Rev Ciencias Médicas [Internet]. 2019 [citado: fecha de acceso]; 23(3): 387-396. Disponible en: <http://www.revcmpinar.sld.cu/index.php/publicaciones/article/view/3882>

## ABSTRACT

**Introduction:** bronchial asthma is a frequent condition; it is considered a health problem due to the high morbidity and mortality rates. The lack of success of Western therapies has caused a high number of patients to turn to Traditional Medicine. The implantation of catgut in acupuncture points is one of the newest techniques applied in the treatment of this disease.

**Objective:** to determine the efficacy of catgut implantation in patients with Moderate or Severe Persistent Bronchial Asthma.

**Methods:** experimental and prospective intervention research in 82 patients with moderate or severe persistent bronchial asthma who met the inclusion and exclusion criteria, randomly divided into two groups of equal numbers. The study group received pharmacological and acupunctural treatment, with implantation of catgut in chosen points according to the traditional diagnosis, following a monthly session from 6 to 8 months. The control group only included pharmacological treatment. The clinical evolution, therapeutic response and use of medications in both groups were compared.



**Results:** in the study group the clinical evolution was favorable in 61 % of the patients, requiring up to three treatment sessions, and 75 % decreased the use of medications. The therapeutic response was good in 65.8 %. In the control group the 41.5 % evolved favorably and 68.3 % increased the use of medications.

**Conclusions:** it was evidenced that the implantation of catgut as an alternative therapy in moderate or severe persistent bronchial asthma is useful and shortens the treatment period, as well as reducing the use of medications.

**MeSH:** ASTHMA; ACUPUNCTURE; ANXIETY; RESPIRATORY FUNCTION TESTS; PATIENT CARE.

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## RESUMEN

**Introducción:** el asma bronquial es una afección frecuente, considerada un problema sanitario por los altos índices de morbilidad. La falta de éxito de las terapias occidentales ha provocado que un elevado número de pacientes acudan a la Medicina Tradicional. La implantación de catgut en puntos de acupuntura es una de las técnicas más novedosas empleadas en el tratamiento de esta enfermedad.

**Objetivo:** determinar la utilidad de la implantación de catgut en pacientes con asma bronquial persistente moderada o severa.

**Métodos:** se realizó una investigación experimental de intervención y prospectiva en 82 pacientes con asma bronquial persistente moderada o severa que cumplieron los criterios de inclusión y exclusión, divididos al azar en dos grupos de igual cantidad. El grupo estudio recibió tratamiento farmacológico y acupuntural, con implantación de catgut en puntos seleccionados según el diagnóstico tradicional, en sesión mensual durante 6 a 8 meses. El grupo control solo recibió tratamiento farmacológico. Se comparó la evolución clínica, respuesta terapéutica y consumo de medicamentos en ambos grupos.

**Resultados:** en el grupo estudio la evolución clínica fue favorable en el 61 % de los pacientes, necesitando hasta tres sesiones de tratamiento, y el 75 % disminuyó el consumo de medicamentos. La respuesta terapéutica fue buena en el 65,8 %. En el grupo control evolucionó favorablemente el 41,5 % y el 68,3 % aumentó el consumo de medicamentos.

**Conclusiones:** se evidenció que la implantación de catgut como terapia alternativa en el asma bronquial persistente moderada o severa, es útil y acorta el período de tratamiento, así como disminuye el consumo de medicamentos.

**DeCS:** ASMA; ACUPUNTURA; ANSIEDAD; PRUEBAS DE FUNCIÓN RESPIRATORIA; ATENCIÓN AL PACIENTE.

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## INTRODUCTION

Bronchial asthma is the most common of chronic conditions among adults and children. It is a chronic, inflammatory, multifactorial respiratory disease characterized by bronchial hyperactivity. <sup>(1)</sup>

Every decade the prevalence increases by 50 %, which could be considered an epidemiological alarm for a non-communicable disease. The WHO estimates that 235 million people currently suffer from asthma, it is estimated that by 2025 this figure will multiply by 45 to 59 % which would represent around 100 million more people with bronchial asthma. <sup>(1)</sup>

Globally, an average of 250,000 deaths from bronchial asthma is reported each year, despite the fact that the introduction of inhaled steroids for treatment had a significant impact on reducing mortality. <sup>(1)</sup>

It is a widespread disease, especially in coastal and developed countries; in New Zealand the prevalence of asthma is above 30 %, in Latin America the average is estimated at 17 %, but with fluctuations between countries ranging from 5 % in some cities in Mexico to 30 % in Costa Rica. <sup>(2)</sup>

In Cuba, it is considered a frequent condition. In 2017, the prevalence of asthma was 93 per 1,000 inhabitants. In the same year it was registered as the second cause of medical attention in health institutions. <sup>(3)</sup>

In Havana, the prevalence rate of bronchial asthma in 2017 was 114.9 x 1. 000 inhabitants and in the age group over 18 years old was 86.24 patients. <sup>(3)</sup>

Dr. Carlos J. Finlay Central Military Hospital, located in Marianao municipality, has an average population of 135.152 inhabitants, 25.570 of whom belong to the age group over 18 years old. A total of 1.629 patients with bronchial asthma were treated in the emergency department of this institution, according to the data collected from the hospital statistics department.

The lack of success of current asthma therapies has resulted in a high number of patients seeking approaches to complementary and alternative medicine to treat their condition.<sup>(4)</sup> There is great interest in Traditional Chinese Medicine and this causes a significant increase in the rate of asthma treatment using this specialty.

Bronchial asthma in traditional Chinese medicine differs from that of Western medicine. Traditional medicine in its pathophysiology states that these paroxysmal dyspnea attacks are due to body energy disorders. <sup>(4)</sup>

For the treatment of bronchial asthma, traditional medicine uses different therapeutic procedures. The implantation of catgut in acupuncture points is one of the newest techniques used in the treatment of this disease.<sup>(5)</sup>

The implantation of suture threads, known as "sowing", is a method of acupuncture therapy proposed 30 years ago by a Chinese medical group in Beijing. It involves inserting a fragment of absorbable surgical suture thread (catgut) into the thickness of the subcutaneous soft tissue corresponding to an acupuncture point. <sup>(6)</sup>

Bronchial asthma occupies an important place in the prevalence of chronic non-communicable diseases. The high cost of medications used in the treatment of bronchial asthma and some medicine associations have harmful effects on health. Therefore, a better therapeutic approach is essential in order to maintain better control and ensure that the treatment can cover a larger number of patients. <sup>(7, 8, 9)</sup>

The objective of the study was to determine the usefulness of catgut implantation in patients with moderate or severe persistent bronchial asthma treated at Dr. Carlos J. Finlay Central Military Hospital in Marianao municipality, Havana province, from October 2016 to September 2018.

Based on the study carried out, it will be evaluated which treatment alternative could be used in patients with moderate or severe persistent bronchial asthma; as well as the clinical progress and time of evolution of these patients, according to traditional diagnosis, by

evaluating the therapeutic response of both groups after treatment and comparing the degree of severity of bronchial asthma in the study group patients, before and after traditional treatment.

## **METHODS**

An experimental prospective intervention research was conducted at Dr. Carlos J. Finlay Central Military Hospital in Marianao municipality, Havana province, from October 2016 to September 2018.

The study target group consisted of 162 patients with a diagnosis of moderate or severe persistent bronchial asthma, attending emergency department of the aforementioned institution. After applying the inclusion and exclusion criteria, the sample comprised 82 patients.

Exit criteria: the onset of serious illnesses or death and the expressed willingness to leave the study.

There were two groups of 41 patients each, the study group (EG) was made up of patients with odd numbers, and the control group (CG) was made up of patients with even numbers.

The study group received pharmacological treatment with anti-leukotrienes and  $\beta$ -2 adrenergic drugs at the recommended dose in traditional medicine and acupuncture treatment, which consisted of the implantation of catgut in the points selected according to the traditional diagnosis, one monthly session during a period of six to eight months. The control group only received pharmacological treatment in the same way as the study group and was followed for the same time.

For the process of the variables, the dependent variable of persistent bronchial asthma, traditional diagnosis (for which the traditional history was made), consumption of medications, clinical evolution and therapeutic response were taken into account.

Moderate: daily symptoms, daily need for inhaled  $\beta$ -2 adrenergic, exacerbations affecting normal activity (more than twice a week) and nocturnal symptoms more than once a week.

Severe: when it presents continuous symptoms, with limited physical activity, frequent exacerbations and frequent nocturnal symptoms.

Clinical evolution classification:

Favorable: if it reaches grade 0 - 1 on the Likert scale and short time of remission of symptoms.

Moderately favorable: if it reaches grade 2 on the Likert scale and average time of remission of symptoms.

Not favorable: if it reaches grade 3 on the Likert scale and long time of remission of symptoms. In order to analyze the behavior of this criterion, a Likert scale was elaborated with a titration from 0 to 3 where:

0- Asymptomatic patient with disappearance of acute exacerbations.

1- Crisis of short duration and slight intensity, with prolonged asymptomatic intervals; daytime symptoms of 1-2 times per week; nocturnal symptoms less than twice a month; normal physical activity and sleep. No hospital admissions.

2- Crisis of short duration and moderate intensity; daytime symptoms three to six times a week; nocturnal symptoms three to four times a month; slight alteration of physical activity (fatigue or dyspnea at medium and great efforts), and sleep. No hospital admissions.

3- Crisis of longer duration and severe intensity; daily symptoms that the patient does not tolerate, without improvement in spite of the treatment, or hospital admission; having significant commitment to physical activity and sleep.

To measure the time of remission of symptoms, it was taken into account the average time from the beginning of treatment to the improvement of symptoms and signs, as well as the number of sessions applied for it:

**Short:** up to three catgut implant sessions.

**Medium:** between four and five sessions.

**Large:** six or more sessions.

Use of medication: it increases when needing a higher dose of the treatment or another medicine in spite of the conventional treatment, as well as the implantation of catgut in the study group, and the conventional treatment in the control group.

It remained the same: it was not necessary to modify the conventional treatment.

It decreases: when a lower dose of the treatment was needed or no other medication was necessary despite the conventional treatment as well as the implantation of catgut in the study group, and the conventional treatment in the control group.

The therapeutic response was considered:

**Good:** patient with clinical improvement, and reduction on medication by more than 50 % of the initial treatment.

**Fair:** patient with clinical improvement, and reduction on medications in less than 50 % of the initial.

**Poor:** same or without clinical improvement, taking medicines without variation or increased. To make the comparative assessment of the clinical evolution between the groups, the test of the signs was used with a level of significance of 0.01 for a reliability of 99 %.

The ethical principles established in the standards related to the handling of clinical histories were complied with. The basic ethical principles of beneficence, non-maleficence, justice and respect for people were met.

## RESULTS

In this research, the largest percentage between the control group and the study group was represented by patients with moderate persistent bronchial asthma. The predominant traditional diagnosis in both groups was the Xu (vacuum) of lung Qi (energy), with 25 patients (61 %) in the study group and 23 patients (56 %) in the control group. The results show that the greatest number of patients obtained improvement in three sessions or less, for 63 % of the total number of patients. Only two patients in the study group needed six or more sessions, one with a diagnosis of spleen Xu (empty) and another with kidney yang Xu (empty).

Clinical criteria and time of remission of symptoms were taken into account in analyzing clinical evolution. The latter were measured in the study group by the number of treatment sessions.

The study group showed a higher percentage of patients with favorable evolution (60.9 %), and only two patients evolved unfavorably. In the control group it behaved in a similar way, but when comparing this parameter from the statistical point of view between both groups, it was verified that the implantation of catgut was more beneficial than the western treatment, when significant statistical differences were found between both, since the value of  $p$  calculated was less than 0.01 for a reliability level of 99 %.

Among the patients who evolved favorably and moderately favorable, the Xu (empty) group of lung Qi(energy) was greater in both the study group and the control group. In patients with unfavorable evolution, the majority corresponded to the control group, nine patients, and only two were from the study group (Table 1).

**Table 1-** Distribution of the studied patients according to the clinical evolution and traditional diagnosis of bronchial asthma at Dr. Carlos J. Finlay Central Military Hospital, Havana- October 2016-September 2018

Traditional Diagnosis	Clinical Evolution											
	Favorable				Fairly favorable result				Not favorable			
	EG		CG		EG		CG		EG		CG	
	T	%	T	%	T	%	T	%	T	%	T	%
XU DE QI OF LUNG	19	76,0	10	58,8	6	42,9	8	53,3	0	0,0	5	55,6
XU OF SPLEEN	1	4,0	2	11,8	0	0,0	2	13,3	1	50,0	1	11,1
XU DE YIN OF KIDNEY	4	16,0	2	11,8	4	28,6	1	6,7	0	0,0	1	11,1
XU DE YANG OF KIDNEY	1	4,0	3	17,6	4	28,6	4	26,7	1	50,0	2	22,2
TOTAL	25	61,0	17	41,5	14	34,1	15	36,6	2	4,9	9	22

P: 0. 00001

Source: a questionnaire designed by the authors

As part of the evaluation of the therapeutic response, the variation in the use of medicines after the treatment starting was evaluated; in the study group the majority of patients (75.6 %) decreased and only 10 patients maintained the same treatment (24.4 %). However, in the control group, the highest percentage (70.3%) had a need to increase on medications and only six were able to decrease it. The economic impact of the proceeding with catgut was demonstrated, based on the decrease on medication observed after treatment, in the patients in the study group, by obtaining a value of  $p$  of less than 0.01 for a reliability level of 99 %.

The therapeutic response was evaluated taking into account the clinical evolution and the variation in the use of medicines; in the study group all the patients who had a favorable clinical evolution (25 patients) decreased the use of medicines. Those with moderately favorable evolution decreased or were maintained with the same treatment. Meanwhile, in the control group, the majority of patients with favorable clinical evolution (11 patients) and moderately favorable (10 patients) had to increase the intake of medicines (Table 2).

**Table 2-** Distribution of patients according to intake of medicines and clinical evolution

Group	Clinical Evolution	According to the intake of medicines						Total	
		Increase		Decrease		Equal			
		No	%	No.	%	No.	%	No.	%
Control	Favorable	11	64,7	4	23,5	2	11,8	17	41,5
	Fairly favorable	10	66,7	2	13,3	3	20,0	15	36,6
	Not favorable	7	77,8	0	0,0	2	22,2	9	22,0
	<b>Total</b>	28	68,3	6	14,6	7	17,1	41	100
Study	Favorable	0	0	25	100	0	0	25	61
	Fairly favorable	0	0	6	42,9	8	57,1	14	34,1
	Not favorable	0	0	0	0	2	100	2	4,9
	<b>Total</b>	0	0	31	75,6	10	24,4	41	100

Source: questionnaire designed by the authors

The therapeutic response was good in the majority of patients in the study group (27 for 65.85 %), 12 patients had regular response for 29.27 %. In the control group 51.22 % had a poor response and 39.02 % had a fair response. Only four patients in this group had a good therapeutic response for 9.76 %. (Table 3)

**Table 3-** Distribution of patients studied according to the therapeutic response

Response	Study Group		Control Group	
	T	%	T	%
Good	27	65,85	4	9,76
Fair	12	29,27	16	39,02
Poor	2	4,88	21	51,22
<b>Total</b>	41		41	

Source: questionnaire designed by the authors

After analyzing all variables, the degree of severity of bronchial asthma in patients in the study group before and after traditional treatment was compared, most patients moved to a lower scale in the western diagnosis of bronchial asthma; from four patients with severe asthma before starting the treatment, three became moderate, and from 37 who were moderate at baseline, 30 ended up with a diagnosis of mild asthma. Only one patient traditionally classified as Kidney Yang Xu did not have a change in scale and remained as severe bronchial asthma. (Table 4)

**Table- 4** Degree of severity in patients suffering from persistent bronchial asthma and traditional diagnosis of the study group before (A), and after (D) treatment

Variable	Traditional diagnosis	No. patients	Scale					
			Severe 3		Moderate 2		Slight 1	
			A	D	A	D	A	D
Persistent bronchial asthma	Xu de Qi of lung	25	-	-	25	3	-	22
	Xu of spleen	2	1	-	1	1	-	1
	Xu de Yin of kidney	8	-	-	8	2	-	6
	Xu de Yang of kidney	6	3	1	3	4	-	1
<b>Total</b>		41	4	1	37	10	0	30

Source: questionnaire designed by the authors

## DISCUSSION

The highest percentage in both groups was represented by patients with moderate bronchial asthma; this coincides with a recent study carried out in Spain, where moderate asthma predominated over severe asthma. <sup>(10)</sup>

The predominant traditional diagnosis in both groups was the Xu (empty) of Qi (energy) of lung, no other work was found that studied the patients according to traditional diagnosis. It is considered that the predominance of this traditional diagnosis in the target population is related to the dysfunction of the lung in the metabolism of energy, since this Zang organ is in charge of governing the Qi (energy) of the whole body and before the invasion of exogenous pathogenic factors or the internal damage of organs by endogenous pathogenic factors, an important imbalance of the energetic status of the organ is produced, which causes associated diverse symptoms included in this syndrome.

The time of remission of the symptoms in the group study according to the traditional diagnosis of the patients was created in three sessions or less for the Xu of Qi (energy) of lung, which represents 63 % of the total of patients, this result agrees with another study that demonstrates improvement and remission of the symptoms in chronic diseases in the first three months of treatment. <sup>(11)</sup>

Xu (empty) Qi (energy) of lung tends to be a less severe form of bronchial asthma. Hence, the patients in the study group into this research have eradicated their symptoms with fewer treatment sessions. <sup>(12)</sup>

Other authors agree with this study, stating that with the application of complementary traditional medicine there are improvements in lung function under exertion, as well as a tendency towards a lower level of anxiety. The immediate results, as well as those obtained



in the follow-up, present traditional medicine as a supportive therapeutic option to achieve asthmatic adults free of symptoms. <sup>(13)</sup>

Specialists in acupuncture from the National School of Medicine and Homeopathy, of the National Polytechnic of México, assure that it is an effective and adequate treatment for chronic conditions due to the fact that it stimulates, in a prolonged way, strategic points (acupuncture) that favor biological communication, as well as the neuro-immunoendocrine response of the organism with a bio-regulatory effect. <sup>(5)</sup>

When evaluating the therapeutic response in relation to the variation of the intake of medicines after starting the treatment, it was shown that, as patients improved with the application of catgut, they needed fewer doses of pharmacological medication. The results obtained in the research coincide with those published by Li Deyang <sup>(14)</sup> in the Chinese Journal of Acupuncture and Moxibustion, where in 216 patients treated with the same pathology (73.5 %) reduced the use of conventional medications and 30.2 % eliminated the intake of medications altogether.

The results of this study are similar to those published by WanYinsu <sup>(14)</sup>, in the Chinese journal of acupuncture and moxibustion of Beijing, when making the clinical observation of 196 cases with the same clinical disease and similar therapeutic procedure, where 82 cases (41.84%) obtained good results, in 101 cases (51.53 %) was effective and only in 13 cases (6.63 %) was unsuccessful.

In conclusion, the most frequent traditional diagnosis was Xu (empty) of lung Qi (energy) in both groups, as these patients had the best clinical evolution. In the study group, the majority of patients evolved satisfactorily, with a short remission time and a decrease in the consumption of medications. Most of the patients in the control group evolved satisfactorily but needed to increase the use of medications. The therapeutic response was good in more than half of the patients in the study group; however, in the control group more than half had a poor response. A large percentage of patients decreased the severity of bronchial asthma after traditional treatment.

#### **Conflict of Interest:**

The authors state that there is no conflict of interest.

#### **Authors' contribution:**

The authors contributed equally to the design of the study.

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