

Clinical effect, safety and mechanisms of BICOM 2000 system to asthma in children

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Objectives

1. To examine the allergen detection, clinical effect, safety in the near future and side effects of the Bicom 2000 system to asthma in children.
2. To explore the mechanism of Bicom 2000 to asthma through evaluation of the changes in serum levels of IL-4, tlgE and IFN-gamma before and after Bicom treatment.

Methods

1. Allergen detection and desensitization

A total of 124 children with asthma and 150 children with asthma associated with rhinitis were selected according to the "national standard for child asthma" formulated by the national child asthma consortium. There were 82 mild, 164 moderate and 28 severe cases. All cases had not been treated with systemic glucocorticoids, antihistaminics or immunomodulators within one week before treatment. All children received allergen test and desensitization with Bicom, together with the standard GINA therapy, which includes 125 microgram fluticasone inhaled, qd-tid, and short-immediate beta-2 R agonist when needed.

2. Mechanism study

A total of 30 children received solely standard GINA treatment and another 30 children received both Bicom treatment and the standard GINA treatment. Serum levels of IL-4, tlgE and IFN-gamma were measured by ELISA before and after treatment.

3. Data Analysis

Data was analyzed by the PSP software for statistical differences.

Results

1. Allergen detection by the Bicom 2000 system

No allergen was detected in only one child. Allergens of 3-15 kinds were detected in the other 273 cases, including 69.39% inhalation allergens, 22.0% food and food additives, 6.7% contact allergens, and 1.28% chemicals. A total of 21 cases received also standard skin allergen test, and a 78.6% positive concordance was observed.

2. Clinical effect after desensitization by the Bicom 2000 system

All children received desensitization therapy with the Bicom 2000 system 6-8 times. Based on improvement of symptoms and reoccurrence in 6 months after treatment, the total effective power was 93.4% and 91.1% after 6 months (Fig. 1). The effective power to asthma is 89.1% and 92.0% to asthma with rhinitis. After the first Bicom treatment, 23.5% cases reported improvement, which increased as more treatment was received.

3. Possible mechanisms of Bicom treatment

Two groups of patients were treated with (A) or without (B) Bicom system in addition to the standard GINA treatment. No statistical difference in age, sex, course and state of illness was detected between the two groups. Serum levels of IL-4, tlgE and

IFN-gamma were measured before and after treatment. No significant difference was found before treatment among the two groups, neither before or after treatment in group B (Figs. 2-4). The tIgE, but not IL-4 and IFN-gamma, level was significantly lower in group A after treatment by the Bicom system than before (Fig. 2, $p < 0.05$). It is also significantly lower than that in group B after standard GINA treatment only (Fig. 2, $p < 0.05$).

4. Side effects

Blood routine, urine routine, liver function, kidney function and myocardiumase were performed before and after the Bicom treatment in a total of 10 children and no significant differences were found. No side effects were observed.

Conclusions

1. Allergen detection by the Bicom system showed high concordance (78.6%) with standard skin test. The treatment is safe, has immediate effect and shows good compliance. It is effective to both asthma and asthma with rhinitis.
2. Inhaled glucocorticoids have remarkable effects on the serum levels of IL-4, tIgE and IFN-gamma before and after treatment. However, when combined with Bicom treatment, level of tIgE, but not IL-4 and IFN-gamma, was significantly lower after treatment.

Key words: Bicom allergy therapy; asthma, clinical effects, safety, tIgE.

Editor's Note: This is a sound study which in itself provides sufficient proof of the effectiveness of the Bicom method. The effectiveness is further supported by a number of similar Chinese studies with varying degrees of evidence. (See literature [Editor's Note]).

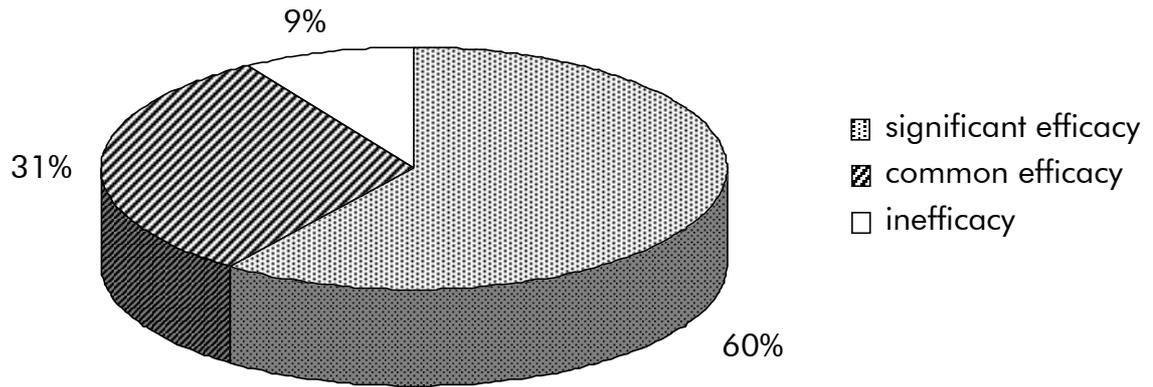


Fig. 1: Curative effect of BICOM 2000 to asthma in 274 children

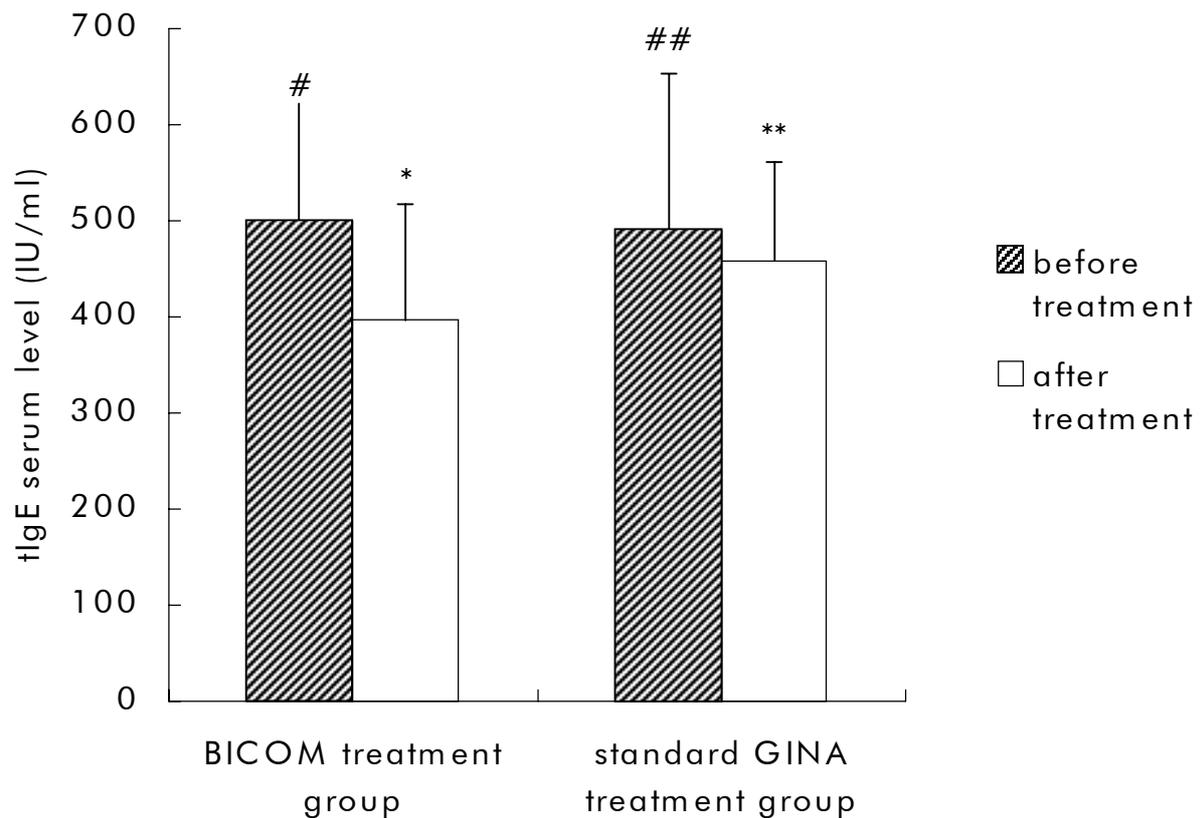


Fig. 2: Two groups' serum levels of tlgE before and after treatment

compared with *: $t = 3.22, p < 0.05$

compared with ##: $t = 0.31, p > 0.05$

compared with **: $t = 0.85, p > 0.05$

* compared with **: $t = 2.80, p < 0.05$

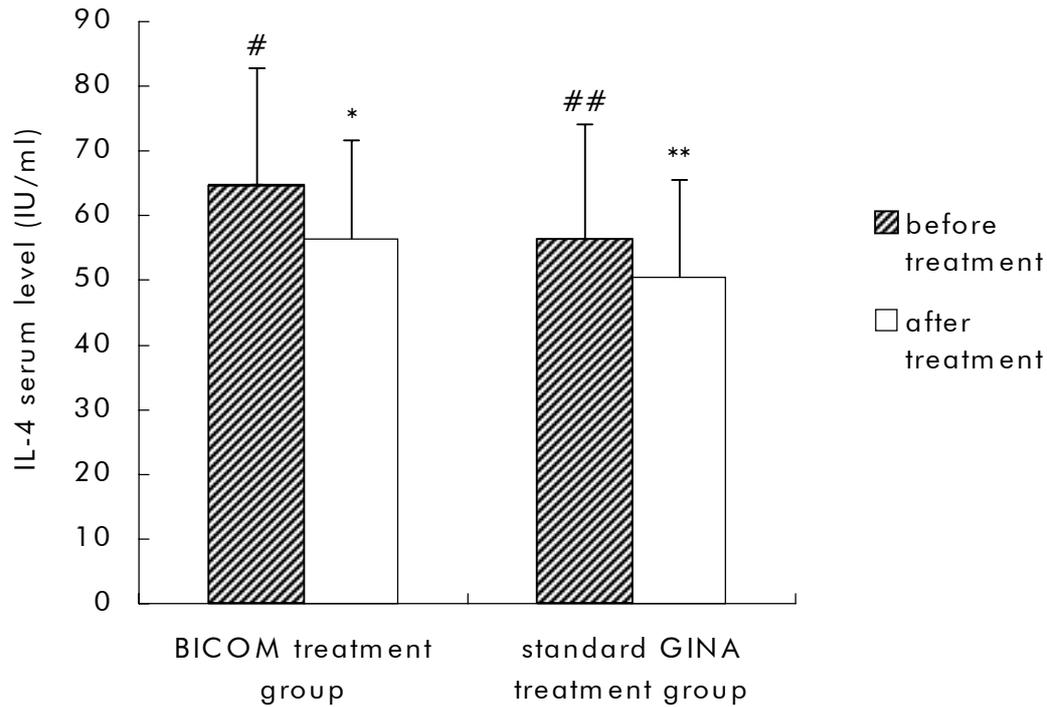


Fig. 3: Two groups' serum levels of IL-4 before and after treatment

compared with *: $t = 1.99, p > 0.05$ ## compared with **: $t = 1.33, p > 0.05$
 # compared with ##: $t = 1.84, p > 0.05$ * compared with **: $t = 1.62, p > 0.05$

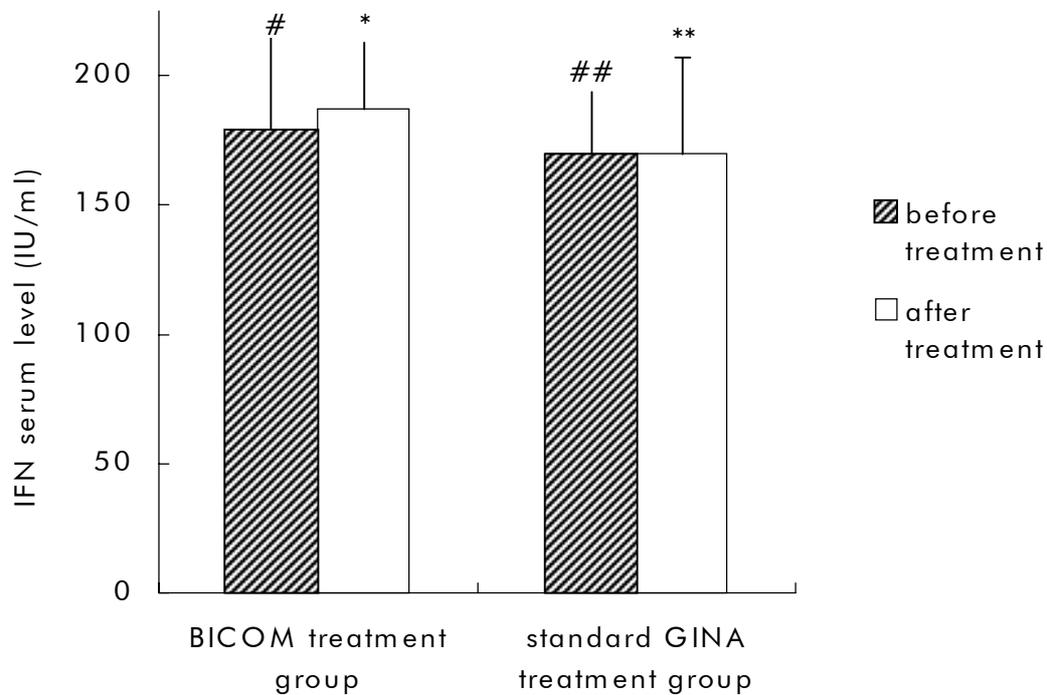


Fig. 4: Two groups' serum levels of IFN before and after treatment

compared with *: $t = 0.79, p > 0.05$ ## compared with **: $t = 0.05, p > 0.05$
 # compared with ##: $t = 0.98, p > 0.05$ * compared with **: $t = 1.89, p > 0.05$

Literature (Editor's Note)

1. Feng Yizhen, Chen Huanzhi, Li Rufeng and Liu Liping (Clinical Academy of the University of Shandong): **The most recent clinical observation of the healing effect using the bioresonance device in 150 cases of children with allergies.**
2. Yuan Ze, Huang Jioh, Wang Haiyan and Yu Chunyan (Department of Paediatrics at Xi'an Central Hospital): **Bioresonance device for the treatment of allergic disorders (154 patients).**
3. Yuan Ze and Wang Haiyan (Xi'an Central Hospital): **Clinical results using the BICOM 2000 bioresonance device (1639 patients).**
4. Huang Shuiming, Sun Zhangping, Fang Yucai: **Clinical observation of the treatment of cold allergies and bronchial asthma in children using the bioresonance therapy device (181 cases).**
5. Yang Jinzhi and Zhang Li (**Research Centre at Jinan Paediatric Clinic, Shandong Province**): **300 examples of treating asthma in children with the BICOM device.**
6. Du Xin, Liu Yuanxia and Yang Jinzhi: **Clinical observation of 79 cases using the bioresonance device to treat allergic skin disorders.**