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Original Research Article

Evaluation of the clinical use and impact of Miao medicine's anti-influenza mask on IgA in human serum and SIgA in nasal mucosa

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Abstract

Purpose: *To investigate the clinical use of anti-influenza mask of Miao medicine, and its effect on human serum immunoglobulin A (IgA) as well as nasal mucosa secretory immunoglobulin A (SIgA).*
Methods: *500 patients without COVID-19 in QianDongNanZhou Hospital of Traditional Chinese Medicine from January 2020 to September 2022 were selected and randomly divided into study and control groups, with 250 patients in each group. Both groups wore masks for three months. Control group was given disposable medical surgical three-layer melt-blown non-woven masks, while study group was given Miao medicine anti-infection masks. Serum IgA and SIgA levels were compared before and after wearing masks in both groups.*
Results: *Prior to intervention, serum IgA and SIgA levels in nasal mucosa were not significantly different ($p > 0.05$). There were also no significant differences in blood IgA levels between control and study groups. Before wearing masks, the study group had higher levels of blood IgA and nasal mucosal SIgA than control group. After wearing masks, nasal mucosa SIgA antibody levels and blood IgA antibody levels were significantly higher in the study group compared to control group ($p < 0.001$). The frequency of adverse responses did not significantly differ between the two groups ($p > 0.05$).*
Conclusion: *Miao medicine anti-infection masks are safe and raise serum levels of COVID-19 IgA antibodies and nasal mucosa SIgA levels in populations susceptible to COVID-19. These properties need to be compared among different races for the purpose of validation.*

Keywords: *Miao medicine, Mask, COVID-19, Immunoglobulin A, Secretory immunoglobulin A*

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INTRODUCTION

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the virus that causes COVID-19 and may infect people to varying degrees. It frequently manifests as an epidemic outbreak and causes fever, coughing, asthma, shortness of breath, moist rales of the lungs, muscular aches, etc. Some data show that SARS-CoV-2 is highly virulent, spreads rapidly, and causes serious harm [1]. In 2022, approximately 1.1 billion to 1.2 billion people in China were infected

with COVID-19. Based on statistics, the global mortality rate of COVID-19 stands at approximately 1.02%, with all provinces and cities in China generally reporting rates lower than the global average [2]. Nevertheless, the impact of COVID-19 should not be underestimated. Some patients may have complications such as myocardial damage, respiratory failure, and even death [3,4]. On the other hand, certain COVID-19 patients have severe symptoms which are challenging to treat, relapse frequently, and with significant impact on their lives and that of residents. Therefore, prevention of COVID-19 is still an important task at present.

Miao medicine is similar to Yingxiang (LI20), and the mask is constructed using *Jatamans valeriana* rhizome, *Herba pogostemonis*, *Radix Angelicae dahuricae*, etc. This mask stimulates nasal absorption of the drug and improves respiratory resistance [5]. At present, the clinical application of Miao medicine anti-infection masks has achieved initial results. Serum immunoglobulin A (IgA) is a monomer that reflect the body's humoral immune function [6]. A powerful antiviral effect of secretory immunoglobulin A (SIgA), which is a dimer joined at the J chain and an effector of mucosal immunity, prevents viruses from attaching to nasal epithelial cells [7]. However, it is not clear whether the anti-infection mask of Miao medicine prevents viral pneumonia by improving serum IgA and nasal mucosa SIgA in populations susceptible to COVID-19. Based on this, 500 cases from COVID-19 susceptible population were chosen to participate in this study, which aimed to investigate the clinical use of anti-influenza mask of Miao medicine, and its effect on IgA and SIgA levels.

METHODS

General information

Inclusion criteria

Patients between the ages of 16 to 65 years, individuals susceptible to COVID-19, and signed informed consent forms to participate in the study.

Exclusion criteria

Patients with difficulty controlling chronic diseases or immunodeficiency, patients with chronic respiratory failure, chronic heart failure, those allergic to the drug or mask components, pregnant or lactating women, individuals with mental or communication disorders, long-term users of immunomodulatory drugs, and patients with a history of nasal trauma and surgery. Additionally, poor compliance, loss of follow-up, and sudden accidents were also considered as exclusion factors.

Sample size

The sample size was calculated using the public formula indicated in Eq 1.

$$\text{Sample size} = (U\alpha+U_\beta)^2 2P(1-P)/(P_1-P_0)^2 \quad \ldots (1)$$

where $\alpha = 0.05$, $\beta = 0.10$, $U_\alpha = 1.96$, $U_\beta = 1.282$, according to the pretest $P_0 = 0.05$, $P_1 = 0.108$, the dropout rate was set as 10 %, so a total of 500 cases were included.

Patients were chosen from COVID-19-vulnerable population between January 2020 and September 2022 which included 263 men and 237 women. The mean age was 45.95 ± 8.55 years. A total of 228 patients had a smoking history, and 192 patients had a drinking history. They were randomly divided into study and control groups with 250 cases in each group. This study was approved by the Ethics Committee of QianDongNanZhou Hospital of Traditional Chinese Medicine (approval no. Yan-2020-01) and followed international guidelines for human studies. Signed written informed consent was obtained from the patients and/or guardians before commencement of study.

Procedures

Both groups wore masks throughout entire trip to avoid entering medium-risk and high-risk areas. After returning home, alcohol disinfectant was sprayed for disinfection, windows were opened for ventilation for 2 h every day, and masks were worn for 3 months. Control group used disposable surgical three-layer melt-blown non-woven masks, while study group used Miao medicine anti-influenza masks containing *Jatamans valeriana* rhizome, *Herba pogostemonis*, *Radix Angelicae dahuricae*, etc. Each mask contained 0.5 g of drug placed in the upper left corner to prevent it from being deposited in the nostrils after wearing. This placement not only prevented denaturation by nasal and oral secretions but also stimulated the Yingxiang point and strengthened nasal orifices through drug absorption.

Evaluation of parameters/indices

Serum IgA and nasal mucosa SIgA levels before and after intervention in the two groups, and the occurrence of adverse reactions were recorded.

Additionally, regular determination of liver and kidney function, blood, stool, and other routine tests were performed to identify any potential complications.

Statistical analysis

Statistical analysis was conducted using SPSS 26.0 software (IBM, Armonk, NY, USA). The K-S test confirmed that measurement data followed a normal distribution and were described as mean ± standard deviation (SD). Independent sample t-tests were used to compare differences between groups, while paired *t*-tests were used to compare differences within each group. Count data were presented as percentages. $P < 0.05$ was considered statistically significant.

RESULTS

General data

There were 12 cases of poor compliance and 7 cases were lost to follow-up in the study group. In the control group, 10 cases had poor compliance, and 7 cases were lost to follow-up and were excluded from this study. There was no significant difference in general data between the two groups ($p > 0.05$) (Table 1).

Serum IgA and nasal mucosa SIgA levels

Before intervention, the level of serum IgA was not significantly different from SIgA in the nasal mucosa ($p > 0.05$) (Table 2 and Figure 1). There was no significant difference in serum IgA between control and study groups (Table 2 and Figure 1). Serum IgA and nasal mucosa SIgA levels after intervention in study group were significantly higher than before intervention (Table 2 and Figure 2). Serum IgA and nasal mucosa SIgA levels in study group were significantly higher compared to control group (Table 2 and Figure 2).

Incidence of adverse reactions

During intervention period, there was 1 case of facial flushing and 1 case of facial pruritus in study group. Furthermore, there were 2 cases of facial flushing, 1 case of facial pruritus, and 2 cases of facial erythema in control group. Adverse reactions were mild, and no special intervention was performed. Liver and kidney function, blood routine, urine and stool routine of the two groups were normal. Incidence rate of adverse reactions in study group was 0.87 % (2/231), and 2.15 % (5/233) in control group; however, this difference was not statistically significant (corrected $\chi^2 = 0.563$, $p = 0.453$).

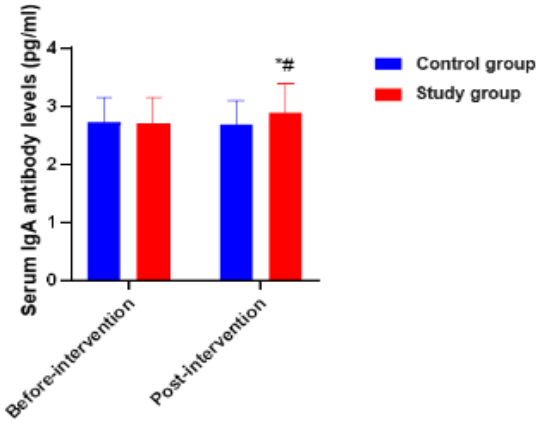

Figure 1: Serum IgA levels before and after intervention in study and control groups. *#$P < 0.05$

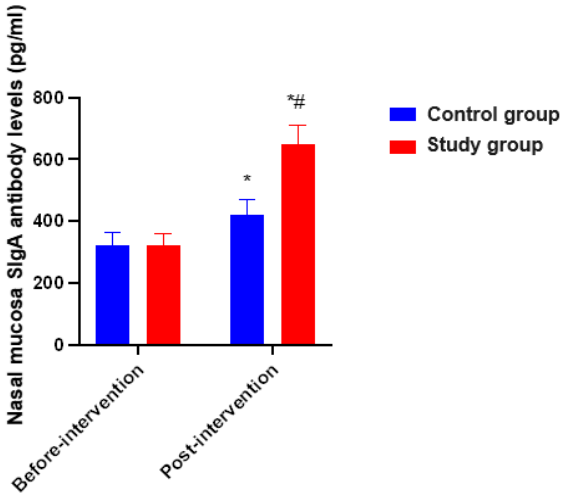

Figure 2: Nasal mucosa SIgA levels before and after intervention in study and control groups. *#$P < 0.05$

Table 1: Comparison of general data between the two groups

General information	Treatment group (N = 231)	Control group (N = 233)	χ^2/t	*P*-value
Sex				
Male	123(53.25)	120(51.50)	0.142	0.707
Female	108(46.75)	113(48.50)		
Age (years)	45.36±8.52	46.71±8.63	1.696	0.091
History of smoking	110(47.62)	106(45.49)	0.211	0.646
History of alcohol use	86(37.23)	90(38.63)	0.096	0.756

Table 2: Serum IgA and nasal mucosa SIgA levels in study and control groups (mean ± SD)

Group	N	Serum IgA (pg/mL)		*T*-value	*P*-value	Nasal mucosa SIgA (pg/mL)		*T*-value	*P*-value
		Before intervention	***Post-intervention***			***Before intervention***	***Post-intervention***		
Study group	231	2.71±0.43	2.89±0.49	4.196	<0.001	321.05±40.05	650.23±60.28	69.13	<0.001
control group	233	2.72±0.42	2.69±0.41	0.780	0.436	320.87±40.02	420.55±51.36	23.37	<0.001
T-value		0.253	4.770	—	—	0.048	44.19	—	—
P-value		0.800	<0.001	—	—	0.961	＜0.001	—	—

DISCUSSION

COVID-19 is an infectious disease that is highly infectious and transmissible across populations [8]. The virus is transmitted through droplets and direct contact. Currently, primary methods of preventing COVID-19 include vaccination, wearing masks, and enhancing resistance [9,10]. Commonly used disposable surgical three-layer melt-blown non-woven masks are used in controlling the spread of SARS-CoV-2 by resisting droplets and body fluid transmission. However, people who are vulnerable to COVID-19 still wear conventional masks during the infection process due to factors such as viral mutations with strong virulence and limited mechanisms of action against SARS-CoV-2 infection [11,12]. Therefore, it is necessary to improve masks to enhance the prevention and control of COVID-19.

According to the theory of traditional Chinese medicine, COVID-19 falls under the category of "*epidemic febrile disease*" due to factors such as body deficiency, invasion of warm and pathogenic elements, the battle between positive and pathogenic factors, endogenous dryness and heat, as well as Yin and fluid consumption. Therefore, to prevent COVID-19 effectively, it is crucial to enhance overall health and strengthen resistance against warm pathogens. The Miao medicine anti-influenza mask was developed based on the improvement of the Miao medicine anti-influenza sachet [13].

Aromatherapy is of great significance in the prevention of infectious diseases. Miao medicine anti-influenza sachet is based on aromatherapy and is composed of *Jatamans valeriana* rhizome, Agastache and angelica dahurica. It shortens the course of influenza patients and not only prevents influenza virus infection but also regulates the expression of type I interferon. *Jatamans valeriana* rhizome regulates *qi* to alleviate pain and dispels wind, dampness, and evil. *Herba pogostemonis* regulates sputum, dehumidification and fire, Radix *Angelicae dahuricae* regulates dehumidification and pus, pain relief, resists *warm evil*, and prevents viral infection. Modern pharmacological studies show that *Jatamans valeriana* rhizome is rich in sesquiterpenes and iridoids, which have antiviral activity and also reduce respiratory inflammation caused by viral infection [14].

Active ingredients in *Herba pogostemonis* prevent and treat COVID-19 [15,16]. There are also antiviral active components in *Angelica dahurica*, which mainly inhibit virus replication, regulate viral proteins and inhibit protease activity [17]. There is evidence that traditional Chinese medicine (TCM) not only controls the immune system and avoids viral pneumonia but also lessens symptoms, severe sickness and even mortality [18]. This study is based on a prescription for a Miao medicine anti-flu sachet constructed into a Miao medicine anti-flu mask, which when administered through the Yingxiang point disperses wind and heat, opens the Tongli nasal orifices, and fends off warm evil in order to meet the goal of lowering COVID-19 occurrence.

This study revealed that serum IgA and nasal mucosa SIgA levels in study group were significantly higher compared to control group after intervention (wearing a mask). In contrast, serum IgA levels in control group after intervention remained the same compared to before intervention. This suggests that conventional masks did not enhance the resistance of the susceptible population to SARS-CoV-2, whereas Miao medicine anti-infection masks were able to improve overall resistance and nasal mucosa local resistance. Thus, Miao medicine anti-influenza masks had a superior effect. The higher the SIgA level in the nasal mucosa, the stronger the resistance of nasal mucosa to SARS-CoV-2, and the better the effect of preventing COVID-19 [19,20]. Wearing a Miao medicine anti-influenza mask allows the nasal mucosa to inhale a substantial amount of antiviral active ingredients, which activates the immune system, increases serum IgA nasal mucosa SIgA levels, and enhances the ability to prevent new coronavirus infection. Even if some patients become infected with the new coronavirus, IgA recognizes and eliminates it promptly, thereby reducing damage and related complications caused by the new coronavirus. After intervention, the serum IgA of control group did not change significantly, while nasal mucosa

SIgA level was higher compared to levels before intervention. The reason for this result may be that the subjects implemented health guidance thereby improving local immunity by adjusting diet and rest patterns. This study also revealed that the adverse effects of study and control groups were mild, and the incidence rate was equal, suggesting that the anti-infection mask of Miao medicine does not increase or aggravate adverse reactions., and may thereby be considered safe for clinical use.

Limitations of this study

Single-center study and low number of participants are the major limitations of this study.

CONCLUSION

Miao medicine anti-influenza mask increases serum IgA and nasal mucosa SIgA levels. Furthermore, it is also safe and may be considered for more studies across different nations for data validation purposes.

DECLARATIONS

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None provided.

Ethical approval

None provided.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflict of Interest

No conflict of interest associated with this work.

Contribution of Authors

The authors declare that this work was done by the authors named in this article and all liabilities pertaining to claims relating to the content of this article will be borne by them.

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