Original Article

The Effect of Magnesium Citrate on %FEV$_1$, %PEFR, and Asthma Control Test Score in Patients with Controlled Asthma and Uncontrolled Asthma

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Abstract

Background: Asthma is one of the most common non-communicable diseases in the world and affected an estimated 262 million people in 2019. Magnesium is one of the nutrients known to improve lung function in asthma by inhibiting the production of proinflammatory cytokines, exhibiting anti-inflammatory benefits, and having beneficial muscle-relaxing and bronchodilatation effects. Measurement of percent predicted forced expiratory volume in 1 second (%FEV$_1$), percent predicted peak expiratory flow rate (%PEFR), and asthma control test (ACT) score is are indicator of lung function. Magnesium citrate may be used as an adjunct therapy in patients with controlled and uncontrolled asthma.

Methods: Clinical trial research with quasi quasi-experimental method using a pre-test and post-test design. The study subjects were 34 controlled and uncontrolled asthma patients at the outpatient clinic of Universitas Sebelas Maret Hospital and dr. Soehadi Prijonegoro Hospital in February - March 2023, using consecutive sampling. The control group (n=17) received standard therapy, while the treatment group (n=17) received standard therapy plus 300 mg magnesium citrate for 42 days. Serum magnesium level, %FEV$_1$, %PEFR, and ACT score were measured at enrollment and on the forty-third day of treatment.

Results: There were significant differences between the treatment group compared to the control group in increasing %PEFR (*P*=0.001), increasing ACT score (*P*=0.011), and increasing %FEV$_1$ (*P*=0.071).

Conclusion: Administration of magnesium citrate to patients with controlled and uncontrolled asthma can increase levels of %PEFR, ACT score, and %FEV$_1$.

Keywords: %FEV$_1$, %PEFR, ACT, asthma, magnesium citrate

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INTRODUCTION

Asthma is a heterogeneous clinical syndrome characterized by chronic inflammation of the airways and a history of respiratory symptoms, such as wheezing, shortness of breath, chest heaviness, and coughing, that vary over time, accompanied by limitation of varied expiratory airflow.[1] The prevalence of asthma is more frequent in males, multiracial, and the black race in children.[2]

Meanwhile, the prevalence of adult asthma is more frequent in women, ages 18–24 years, multiracial, and black. Educational and economic background impact the prevalence of adult asthma.[2] The onset of asthma before age 10 is 50%, while adult-onset asthma is often associated with rhinitis, smoking, weight gain, occupational exposure, and the use of certain medications.[3,4]

The underlying mechanism of asthma is the presence of complex multifactorial disorders with etiologies associated with the interaction of genetic susceptibility, host factors, and environmental exposures.[1,3] A characteristic sign of asthma is the discovery of bronchial hyperresponsiveness (BHR), which is a state of excessive narrowing of the airways, causing increased airflow resistance and decreased airflow.[5]

Lung function tests confirm the diagnosis of asthma if expiratory airflow limitations are found that vary in terms of percent predicted forced expiratory volume in 1 (%FEV$_1$) or percent predicted peak expiratory flow rate (%PEFR). Variability refers to the

improvement and/or worsening of pulmonary symptoms and function. Asthma patients had a %FEV_1 value of <80% of the predicted value on spirometry examination.[3]

Asthmatic patients experience increased BHR due to increased acetylcholine and histamine production, increased calcium ion influx in airway smooth muscle, and increased production of proinflammatory cytokines.[6] Magnesium administration is beneficial in asthma because it inhibits the production of proinflammatory cytokines, exhibits anti-inflammatory benefits, and has muscle-relaxing and bronchodilatation effects through calcium antagonist effects or beneficial adenylyl cyclase activation in the management of asthma patients.[7] The Institute of Medicine (IOM) and the U.S. Food and Nutrition Board set the upper limit for magnesium supplementation at 350 mg/day.[8]

The biological half-life of magnesium in the body is approximately 42 days, so correction of magnesium deficiency requires long-term supplementation.[9] A healthy person needs to consume 5–7 milligrams of magnesium per kilogram of body weight (mg/kg) per day to maintain magnesium balance.[10] A study by Fathi et al in Iran concluded that supplementation of magnesium citrate at a dose of 340 mg/day for two months in mild and moderate asthma patients increased forced vital capacity (FVC), FEV_1, and decreased the ratio of FEV_1/FVC.[11]

Busuttil's study in Australia summed up the results of several predecessor studies and showed that magnesium inhibited interleukin-5 (IL-5), interleukin-13 (IL-13), tumor necrosis factor-α (TNFα), interleukin-1 (IL-1), and interleukin-8 (IL-8) secretion, and weakened airway neutrophil activation in asthma.[12,13] Kilic et al's study in Turkey showed a significant association that FEV_1, %FEV_1, and PEFR were lower in the group of hypomagnesemia-stable asthma patients than in the normomagnesemia-stable asthma patient group.[6]

The degree of asthma control can be assessed using the five-question asthma control test (ACT) questionnaire with well-controlled, poorly controlled, and very poorly controlled asthma classifications.[1] ACT scores correlate well with spirometry test results to assess asthma control levels.[3] A study by Daliparty et al in India showed a positive correlation between serum magnesium levels and asthma control levels.[14]

The modality of nutritional therapy in asthma patients is still not widely studied. Therefore, this study was conducted to determine the effect of magnesium citrate administration on %FEV_1, %PEFR, and ACT scores in controlled and uncontrolled asthma patients. The results of this study are expected to be used as a basis for the use of magnesium citrate as part of therapy for asthma patients to achieve an adequate and optimal treatment.

METHODS

This research is a clinical trial with a quasi-experimental method with a pre-test and post-test design approach in the treatment group and control group. The study was conducted at the lung clinic of Universitas Sebelas Maret Hospital, Surakarta, and the lung clinic of dr. Soehadi Prijonegoro Hospital, Sragen, starting on February 1st, 2023.

The subjects of the study were patients with controlled and uncontrolled asthma. Determination of research samples by consecutive sampling until a certain period, until the required number of patients is met. The sample consisted of 34 patients, consisting of a control group (n=17) receiving standard therapy alone and a magnesium group (n=17) receiving standard therapy and magnesium citrate supplementation of 300 mg for 42 days.

The inclusion criteria for this study are patients who have been diagnosed with asthma in lung clinics, men and women aged ≥18 years, and who are willing to be included in the study. Exclusion criteria are asthma accompanied by acute respiratory tract infections such as pneumonia and chronic respiratory infections such as tuberculosis and bronchiectasis, chronic lung diseases such as COPD and lung tumors, smokers, alcohol users, pregnant, breastfeeding, using diuretics, asthma with heart disease, hypertension, liver cirrhosis, diabetes

mellitus, and chronic kidney failure, as well as clinical gastrointestinal disorders such as nausea, vomiting >5x/day with or without diarrhea. The criteria for discontinuation were that subjects experienced severe or life-threatening exacerbations that required hospital treatment, were no longer tracked during follow-up, or resigned, and side effects of magnesium appeared during the study, such as hypotension, redness, dry mouth, malaise, headache, persistent diarrhea, muscle pain, and muscle contractions.

Controlled and uncontrolled asthma sufferers who are diagnosed and meet the inclusion criteria are described as the aim and objectives of the study. Patients who agree are asked to sign informed consent. The control and treatment groups were examined for serum magnesium levels, FEV_1 examination with spirometry, PEFR examination with peak flow meter, and ACT questionnaire assessment at baseline and 42 days later.

Data analysis was performed using SPSS version 26 for Windows. All numerical data of the study were subjected to normality tests using the Shapiro-Wilk normality test and Levene's homogeneity test. This study used paired t-test for normal paired samples and Wilcoxon tests for abnormal paired samples, as well as unpaired t-test on normal unpaired samples and Mann-Whitney tests on abnormal unpaired samples. The categorical research data were tested with the Mann-Whitney test for ordinal data scales and the homogeneity test of Levene's test. This study has obtained approval from the health research ethics committee of dr. Moewardi General Hospital, as stated in the Ethics Review Approval Letter No. 53/I/HREC/2023.

RESULTS

Thirty-seven subjects met the inclusion criteria. Two subjects from the magnesium group experienced discontinuation due to drug side effects in the form of headaches, while in the control group subject obtained 1 discontinuous subject due to difficulty obtaining a post-treatment venous blood sample. The subjects analyzed at the end of the study were 34 subjects, consisting of 17 magnesium subjects and 17 control subjects.

Qualitative research variables with a categorical scale were described with frequency and percentage numbers, then compared between the treatment group and the control group with the chi-square test. Quantitative characteristic variables with numerical scales are described with mean and standard deviation, then compared to the magnesium group and control group with an independent samples t-test if they meet the normality requirements or the Mann-Whitney test if they do not meet the normality requirements. Table 1 shows the basic characteristics of the subjects.

Table 1. Characteristics of the research subject

Variabel	Magnesium (n=17)	Control (n=17)	*P*
Sex[a]			
Men	5 (29.4%)	5 (29.4%)	1.000
Women	12 (70.6%)	12 (70.6%)	
Age[b]	40.00±13.95	34.88±10.48	0.235
Body Mass Index			
Normoweight	9 (52.9%)	10 (58.8%)	
Overweight	2 (11.8%)	5 (29.4%)	0.409
Obese	6 (35.3%)	2 (11.8%)	
Education[c]			
Uneducated	1 (5.9%)	0 (0.0%)	
Elementary School	2 (11.8%)	1 (5.9%)	
Junior High School	3 (17.6%)	3 (17.6%)	0.527
Senior High School	1 (5.9%)	4 (23.5%)	
University	10 (58.8%)	9 (52.9%)	
Drugs amount			
≤2 drugs	12 (70.6%)	13 (76.5%)	0.527
>2 drugs	5 (29.4%)	4 (23.5%)	
Asthma control			
Uncontrolled	2 (11.8%)	2 (11.8%)	1.000
Controlled	15 (88.2%)	15 (88.2%)	
Asthma duration [c]	15.00±10.27	13.06±11.56	0.500
Symptom			
Dyspnea[a]	2 (11.8%)	3 (17.6%)	1.000
Cough[a]	9 (52.9%)	4 (23.5%)	0.078
Chest tightness	2 (11.8%)	4 (23.5%)	0.656
Tired easily	5 (29.4%)	6 (35.3%)	0.714
Nausea/vomiting	0 (0.0%)	1 (5.9%)	1.000
Nasal congestion	4 (23.5%)	2 (11.8%)	0.656

Note: [a]chi-square test; [b]independent t-test; [c]Mann-Whitney

In the magnesium group, the %FEV_1 pre-test results were obtained on average 79.15±18.72, and the average post-test was 91.37±18.24. The difference in change in %FEV_1 post-pre treatment group was found to have increased by an average of

12.22±9.12, and the increase was statistically significant with *P*≤0.001. The treatment group experienced a higher %FEV_1 increase (12.22±9.12) compared to the control group (5.03±12.94), but the comparison of the difference in change in %FEV_1 increase did not show a statistically significant difference, with *P*=0.071. Table 2 shows the difference in post-pre %FEV_1 between the magnesium and control groups.

Table 2. Measurement of %FEV_1 before, after, and the difference between the post-pre and the control group

Group	%FEV_1		*P*	%FEV_1 difference
	Pre	Post		
Magnesium	79.15±18.72	91.37±18.24	<0.001[b*]	12.22±9.12
Control	79.34±32.28	84.38±23.88	0.128[b]	5.03±12.94
P	0.983[a]	0.334[a]	---	0.071[a]

Note: [a]independent t-test; [b]dependent t-test

The %PEFR pre-test results were obtained on average 70.33±19.28, and the average post-test was 78.54±19.70 in the magnesium group. The difference in post-pre %PEFR change was found to have increased by an average of 8.21±13.30, and the increase was statistically significant with *P*=0.022.

Based on the results, it was found that the magnesium group experienced a higher percentage increase (8.21±13.30) compared to the control group (-4.48±6.74), which tended to decrease. The comparison of the difference in the change in %PEFR increase shows a statistically significant difference, with *P*=0.001. Table 3 shows the difference in post-pre %PEFR between the magnesium and control groups.

Table 3. Measurement of %PEFR before, after, and the difference between the post-pre and the control group

Group	%PEFR		*P*	%PEFR difference
	Pre	Post		
Magnesium	70.33±19.28	78.54±19.70	0.022[c*]	8.21±13.30
Control	77.53±21.36	73.06±22.29	0.015[c*]	-4.48±6.74
P	0.309[a]	0.453[a]	---	0.001[b*]

Note: [a]independent t-test; [b]Mann-Whitney test; [c]dependent t-test

In the magnesium group, the ACT pre-test results obtained an average of 19.00±3.22, and the average post-test was 22.12±1.73. The difference in post-pre ACT changes in the magnesium group was found to have increased by an average of 3.12±2.06, and the increase was statistically significant with *P*≤0.001.

Based on the results, it was found that the magnesium group experienced a higher increase in ACT (3.12±2.06) compared to the control group (0.41±3.89), and the comparison of the difference in changes in the increase in ACT showed a statistically significant difference, with *P*=0.011. Table 4 shows the difference in post-pre ACT scores between the magnesium and control groups.

Table 4. Measurement of ACT score before, after, and the difference between the post-pre and the control group

Group	ACT score		*P*	ACT difference
	Pre	Post		
Magnesium	19.00±3.22	22.12±1.73	<0.001[c*]	3.12±2.06
Control	19.53±4.32	19.94±5.47	0.324[d*]	0.41±3.89
P	0.688[a]	0.444[b]	---	0.011[b*]

Note: [a]independent t-test; [b]Mann-Whitney test; [c]dependent t-test; [d]Wilcoxon test

Pre-test magnesium levels were obtained on average 2.14±0.19, and post-test results averaged 2.36±0.27 in the magnesium group. The difference in changes in post-pre magnesium levels was found to have increased on average by 0.22±0.33, and the increase was statistically significant with *P*=0.014. The magnesium group experienced an increase in magnesium levels (0.22±0.33) compared to the control group (0.06±0.31), but the comparison of the difference in changes in magnesium increase did not show a statistically significant difference, with *P*=0.171. Table 5 shows the difference in post-pre magnesium levels between the magnesium and control groups.

Table 5. Measurement of serum magnesium level before, after, and the difference between the post-pre and the control group

Group	Magnesium level		*P*	Magnesium level difference
	Pre	Post		
Magnesium	2.14±0.19	2.36±0.27	0.014[b*]	0.22±0.33
Control	2.21±0.17	2.27±0.30	0.402[b]	0.06±0.31
P	0.306[a]	0.379[a]	---	0.171[a]

Note: [a]independent t-test; [b]dependent t-test

DISCUSSION

Asthma has multiple phenotypes defined based on a combination of clinical, demographic, and pathological characteristics.[2] The phenotype characteristics of asthma are important for understanding the etiology of asthma, identifying specific causes of asthma, guiding the development

of new therapeutic measures that will be effective in all asthma patients, and enabling better management and prevention of asthma.[15]

T2-high inflammation is associated with increased eosinophils in the airways and peripheral blood, whereas non-Th2 inflammation is associated with neutrophilic or paucigranulocytic cells in the airways.[16,17] The presence of magnesium can inhibit the production of proinflammatory cytokines, exhibit anti-inflammatory benefits, and have muscle-relaxing and bronchodilatation effects through calcium antagonist effects or adenylyl cyclase activation that are beneficial in the management of asthma patients.[7]

Spirometry confirms the diagnosis of asthma if expiratory airflow limitation is found as indicated by a decrease in the FEV_1/FVC ratio of <75%, which varies in terms of FEV_1 or peak expiratory flow (PEF) values.[1,3,18] The degree of asthma control can be assessed using the ACT questionnaire, which has a good correlation with the results of spirometry examination to assess the level of asthma control with a well-controlled, poorly controlled, and very poorly controlled asthma classification.[1,3,19]

The study had a proportion of women, the most at 12 patients (70.6%) in each group. The results of this study are consistent with Morris' data that the prevalence of asthma is greater in females after puberty, and the majority of adult-onset cases diagnosed in people older than 40 years occur in females.[20] Chapman et al's study in Australia, Canada, China, and the Philippines on 1216 asthma patients, Navratilova's study in Surakarta on 30 asthma patients, and Nurwidiasih's study in Surakarta on 32 asthma patients also showed that the characteristics of the study subjects were dominated by women by 59.6%, 63.3%, and 62.5% respectively.[21–23]

The mean age of patients in the magnesium group was 40.00±13.95 years, and in the control group, 34.88±10.48 years. Two-thirds of all asthma cases are diagnosed before the patient turns 18.[20] A study by Chapman et al showed that 94.6% of 1216 subjects were diagnosed with asthma at an average age of 17.5 years, with an average age of all study subjects of 43.1 years.[21]

Body mass index in the magnesium and control group patients was mostly normal weight, which was 52.9% and 58.8% respectively. In this study, obese subjects were found to be as much as 35.3% in the treatment group and 11.8% in the control group. Piuri et al's study in Italy explained that obese patients are more at risk of hypomagnesemia due to unhealthy dietary patterns high in calories but low in micronutrients.[24]

In this study, there were no subjects with magnesium deficiency in the obese group, which may be caused by dietary factors with sufficient daily magnesium content. Besides that, obese patients in this study were also excluded from comorbid diabetes and hypertension, which accompany patients with magnesium deficiency.[25]

Subject education background ranging from not attending school to a doctoral degree. As many as 58.8% of the treatment group subjects and 52.9% of the control group subjects received tertiary education. There was no significant difference in education level between patients in the two groups. The proportion of patients who used <2 drugs daily in the magnesium group was 70.6% and 76.5% in the control group, and there was no significant difference. The two types of drugs used are mostly control drugs containing steroids and β2 agonists.

This study had a homogeneous distribution of the characteristics of the degree of control of asthma subjects, namely 2 patients (11.8%) with uncontrolled asthma, 10 patients (58.8%) with partially controlled asthma, and 5 patients (29.4%) with fully controlled asthma in both groups. There was no significant difference in asthma duration between the magnesium and control group patients, with an average of 15.00±10.27 and 13.06±11.56 years, respectively.

The %FEV_1 value in the treatment group was higher compared to the control group after treatment, but the results of the difference test by increasing the difference %FEV_1 value between the 2 groups showed results that were not significantly different (P=0.071). In the post-test of the treatment group, 15 subjects (88.23%) experienced an increase in

%FEV_1 and 2 subjects (11.77%) experienced a decrease in %FEV1. Meanwhile, in the control group, 8 subjects (53.33%) experienced an increase in %FEV_1 and 7 subjects (46.66%) experienced a decrease in value. This study follows Abuabat et al's systematic review of 5 meta-analysis studies, where the effect of oral magnesium supplementation was assessed at weeks 4, 8, 12, and 26, and obtained a statistically significant increase in FEV_1 values at 8 weeks of treatment.[26]

Smooth muscle relaxation is the most relevant mechanism of magnesium in airway disease. Studies on vascular smooth muscle show that these effects are dose-related and mediated by competition for calcium entry through voltage carriers and receptors on cell membranes and by inhibition of intracellular calcium release from the sarcoplasmic reticulum.[27,28] This effect is complemented by other functions of magnesium, which may lead to bronchodilation and reduction of airway reactivity through indirect effects on airway smooth muscle through inhibition of cholinergic transmission, promotion of nitric oxide release, or through reduction of airway inflammation through prostacyclin production effects and stabilization of mast cells and T lymphocytes.[27]

The results of the difference test for the increase in %PEFR between groups showed a significant difference with *P*<0.001. The results of this study showed that in the treatment group, 12 subjects (70.58%) experienced an increase in %PEFR and 5 subjects (29.42%) experienced a decrease in %PEFR, while in the control group, 5 subjects (29.42%) experienced an increase in %PEFR and 12 subjects (70.58%) experienced a decrease value.

This study follows under study by Kazaks et al in the United States, which examined 55 patients with mild and moderate persistent asthma with magnesium tablets 340 mg for 6.5 months, with the results showing an increase of 5.8% in the value of predicted PEF, with *P*=0.003. This is further evidence of decreased airway resistance in the magnesium treatment group.[29]

The mean value of %PEFR predicted post-test value of *P* of the magnesium and control group was 78.54±19.70 and 73.06±22.29, which means that <80% of the best PEFR and is still categorized as moderate persistent asthma spectrum. In the post-test of this study, there were 11 subjects (64.70%) magnesium group and 9 subjects (60%) control group who had a %PEFR of <80%. When compared with the %FEV_1 parameter, it can be said that the use of spirometers is more accurate and consistent than peak flowmeters. This is possible due to better tool accuracy and regular calibration checks.

The results of this study are different from research by Fogarty et al in the United Kingdom in 300 asthma patients given magnesium amino chelate supplementation 450 mg, there was no significant difference in the absolute value of morning and evening PEF at weeks 4, 8, 12, and 16.[26,28] Subjects may be well controlled with conventional asthma medications, so magnesium supplementation does not need to be added.[28]

Asthma control test scores in the treatment group were higher compared to the control group after treatment. The results of the difference test for the increase in ACT scores between groups showed significantly different results with *P*=0.011.

There has been no preliminary research on the effect of magnesium on the ACT scores of asthma patients, but several studies have proven the benefits of oral magnesium supplementation in improving the clinical symptoms of asthma, where the clinical symptoms of asthma, which can be measured through the ACT questionnaire. Kazaks et al's study in the United States on 55 mild to moderate persistent adult asthma patients who received magnesium supplementation for 6.5 months found significant improvements in subjective measurements of quality of life and asthma control through the asthma quality of life questionnaire (AQLQ).[26,29]

A systematic review by Stahl et al in Sweden explained that most studies found no significant correlation between objective measurements of asthma management and subjective asthma symptoms and concluded that objective clinical measurements and subjective asthma symptom scales provide different types of information about

asthma status. Therefore, objective measurements still provide the best information about a patient's asthma severity and status.[30]

Some studies in children also support the benefits of magnesium in improving asthma symptoms. In a study by Gontijo-Amaral et al in Brazil, patients with persistent childhood asthma had fewer asthma exacerbations and salbutamol use compared to the placebo group.[31] Petrov et al's study in Russian with uncontrolled and partially controlled pediatric asthma patients with magnesium deficiency for 6 months decreased the frequency of exacerbations (P=0.02), and increased the number of asthma symptom-free days (P=0.145) compared to the group without magnesium deficiency correction.[32]

LIMITATION

The study did not observe the diet of the study subjects, the regularity of the study subjects in the standard treatment of asthma, environmental factors, or psychosocial factors. To obtain the optimal dose of magnesium and treatment time, this study requires more research subjects with dose stratification and length of treatment time, as well as grouping treatments based on the level of asthma control or asthma severity, so that analysis of the benefits of magnesium can be carried out at various levels of asthma control or severity. The study requires measurements of intracellular total magnesium levels that more accurately assess a person's total body magnesium levels.

CONCLUSION

Based on this study, magnesium citrate affects lung function as measured by %FEV_1, %PEFR, and ACT score. Magnesium citrate supplementation had a positive and statistically significant effect on %PEFR and ACT score in controlled and uncontrolled asthma patients.

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