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A Study of the Impact of Magnesium Supplements on Asthma Control

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Abstract:-

- ***Background*:**

In the recent studies, the relationship between the magnesium and asthma has been more considered; hence, the present research has aimed to study this issue.

- ***Methodology*:**

The study is a Randomized double blind placebo control trial, which has been conducted on the asthmatic patients who have been divided into two groups: group one consisting of those who have taken placebo and group two including those who have taken magnesium supplement. In the beginning and during the weeks 4, 8 and 12, FVC, FEV1, FEV1/FVC and ACT score have been measured.

- ***Results*:**

40 patients have been studied in two equal groups. The improvement rate of FEV1/FVC has been gradually increased in group2 and was significantly higher than group1 in the week 12. It was also higher in week 4 but not significantly. Moreover, according to FVC ratio, in weeks 4 and 12, the cure rate of the group2 was not significantly higher; however, it was significantly higher in the 8th week. The ACT score of group2 has also significantly increased in comparison to it in 4 weeks before the beginning of the study.

- ***Conclusion*:**

It seems that the magnesium supplement is helpful in improving the clinical and spirometric measurements of asthmatic patients.

Keywords:- *Asthma; Magnesium Supplement; Spirometry; ACT Score.*

I. INTRODUCTION

Asthma is a common disease and, currently, almost 300 million people are suffering from asthma all around the world and its prevalence is rising. It is more prevalent in the developing countries and also among children. It is caused by the acute or chronic inflammation of bronchi, which results into airflow obstruction. Its clinical symptoms is BHI (Bronchial Hyper Sensitivity Increase) as well as elevated IgE, both are related to the patient's genetics [1, 2]. The main objectives of curing asthma are to prevent the emergence of symptoms in the patient, to help the lung to go back to its natural function, to aid the patient to regain power to do her/his natural activities, to avert the relapse of the disease, and to lessen the side effects [3-7]. Short-Acting Beta-Agonists (SABAs), such as Salbutamol are the first-line therapy of the symptoms of asthma. Inhaled Corticosteroids (ICSs) are the first-line therapy of patients suffering from persistent asthma who just need to take a beta-agonist [8]. The medications applied in curing asthma cause a decline in the magnesium value, special in the acute form of disease [9, 10]. Oral and IV forms of Beta-Agonists cause the urinary secretion of magnesium much more than the inhaled form of the drug [11-17].

Magnesium, as the second major intracellular cation, can help the improvement of asthma control as a result of its interaction with calcium and its impact on the cell membrane, and owing to its bronchodilatory function and anti-inflammatory properties. In fact, magnesium is a smooth muscle relaxant factor of airways [18,19,3]. In competition with calcium, on one side, it causes the inhibition of calcium release from sarcoplasmic reticulum network and, on the other side, through the broncho dilation, it causes a decline in bronchospasm, which, eventually, is effective in the decrease of asthma attacks [20-27]. The results of epidemiologic studies show that most asthmatic patients have low magnesium supply [7,28,29]. And, today, IV form of magnesium is widely prescribed during asthma attacks in the ERs of hospitals [1, 30, 31]. However, few studies have been conducted on the effectiveness of magnesium supplements on the lung function of asthmatic patients, magnesium supplements have not been prescribed as an auxiliary treatment. It may be due to the fact that the mechanism of the effectiveness of oral magnesium on asthmatic patients' lung function is still obscure. Also, few interventional studies have been done on the short-term or

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single doses forms of magnesium supplementation [8, 32,33], which indicate an improvement in the treatment of bronchospasm related to exercises, airways hypersensitivity, and asthma [12,34].

According to the above-mentioned, since the physiopathology of the magnesium effects on asthma control is mostly recognized through its bronchodilatory function and anti-inflammatory properties, and there are much evidence regarding the concomitance of asthma and magnesium deficiency in epidemiologic studies, few studies have been conducted on the effects of oral magnesium on long-term control of asthma. Consequently, the present research has aimed to investigate these effects.

II. MATERIALS AND METHODS

The present research has been a double-blind, placebo-controlled randomized trial, which was conducted on patients suffering from moderate to severe asthma, aged between 18 to 60, in the Lung disease clinic of Imam Khomeini Hospital of Sari city. The severely asthmatic patients have been diagnosed by the pulmonologist, who is the university academic member and based on WHO criteria, including those who required high-dose of inhaled corticosteroid (with/without systemic corticosteroid) to prevent the progress of disease to its uncontrolled condition, or those patients whose disease has remained uncontrolled despite medical treatment [12]. The paints have been divided into two groups: group 1 which was the control group (receiving placebo) and group 2 including those receiving magnesium supplementation.

With the standard deviation of peak flow being 40 lit/min, and the sample drop rate being 25 percent, 40 patients have been studied in two mentioned groups.

Both patients and the researcher have not been aware of the type of medication (magnesium supplementation). The placebo was prepared similar to the magnesium supplementation in size and colour by the faculty of pharmacy of Mazandaran University of medical sciences.

Three follow-up methods for the response to medication have been applied: Parameters of Spirometry (FEV1, FVC) 2- PEFR measurement by peakflowmeter 3- Asthma Control Test Questionnaire.

ACT questionnaire is designed a standard mixed questionnaire based on patients' symptoms, their need for using life-saving medication (such as salbutamol, etc.), the impact of the disease on patients' daily activity and patients' own evaluation of the asthma control. Each item has five points and, at the end, patients have been categorized based on the score which was between 5 to 25 (meaning complete control). Score more than 19 showed desirable control. The reliability of the test was 0.77 and its internal consistency was 0.84-0.85 [13, 14,35,36].

The research was conducted individually as much as possible and it was done in a different time of the day for each individual, namely: 1- after the refusal to take bronchodilators of Beta Agonists with short-term effects for 4 hours; 2- after the refusal to take bronchodilators with long-term effect for 12 hours; 3-after the refusal to take antihistamines for 24 hours; 4- taking all asthma drugs regularly and without change. Criteria for going out of the test includes taking oral corticosteroids, using diuretic, suffering from renal failure, CHF, taking magnesium supplementations during last three months, having cigarette smoking history (10 packs per year or more), and pregnancy or pregnancy decisions.

Statistical analyses were done using SPSS 18. Results were shown as mean+ the standard error. Paired students T, ANOVA, repeated measured and Chi-square tests were applied for the statistical analysis. The difference $P<0.05$ was regarded as statistically significant.

III. RESULTS

Finally, 40 patients in 2 groups (each 20 people) were studies, which included 15 men (37.5 percent) and 25 women (62.5 percent): the group taking magnesium supplementation included 6 men (30 percent) and 14 women (70 percent) and the placebo group included 9 men (45 percent) and 11 women (55 percent). The median age of the patients was 38/00±8/45 and it was 37/95±7/68 in the magnesium supplementation group and 38/05±9/36 in the placebo group, which meant that there was no significant difference between two groups (p=0/971). Table 1 shows the primary and demographic information of the patients, according to which the disease severity in 60% of patients was average and in 40% was high. Also, asthma attacks in 60% of patients happened once a year and in 40% more than once.

Table 1 The Primary and Demographic Information of the Patients.

Variable		Frequency					
		Magnesium group		Placebo group		Total	
		Number	percent	Number	percent	Number	percent
Residence	City	7	35%	6	30%	13	32.5%
	Village	13	65%	14	70%	27	67.5%
Cigarette Usage	Yes	0	0%	0	0%	0	0%
	No	20	100%	20	100%	40	100%
Family History	Yes	5	25%	3	15%	8	20%
	No	14	75%	17	85%	32	80%
Medication History	Yes	20	100%	16	80%	36	90%

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	No	0	0%	4	20%	4	10%
Duration of symptoms	More than once a weak	12	60%	12	60%	24	60%
	Every night	8	40%	8	40%	16	40%
Symptoms at night	Yes	12	60%	12	60%	24	60%
	No	8	40%	8	40%	16	40%
Bronchodilators usage	Yes	12	60%	12	60%	24	60%
	No	8	40%	8	40%	16	40%
Asthma Severity	Average	12	60%	12	60%	24	60%
	High	8	40%	8	40%	16	40%
Number of Asthma Attacks	Once a day	12	60%	12	60%	24	60%
	More than once a day	8	40%	8	40%	16	40%

When entering the research, all patients had the FEC1/FVC less than 70 percent. In addition, in both groups, the FEV1 of 40% of individual was 60 percent and in 60% was between 60-80 percent.

Table 2 shows the comparison of the ACT score of asthmatic patients before and after the intervention. According to this table and Paired T test, ACT in the magnesium supplementation group had a significant increase in all weeks in comparison to the previous four weeks. While in the placebo group, there was no significant difference in ACT in different weeks. Moreover, according to the Anova test, there was no significant difference between two groups in any week, whereas this difference in the week 12 was more as to the beginning of the research. According to the repeated measured test, although an increasing trend was observed in ACT, the difference between the two groups was not significant in the whole process (P=0.732) (figure 1).

Table 2 The Comparison among the ACT Scores of the Asthmatic Patients before and after the Intervention.

Time of measurement	**Magnesium Group**		**Comparison of different week in Magnesium group**	**Placebo group**		**Comparison of different week in placebo group**	**Comparison Between the two groups**
	mean	**Standard deviation**	**P.Value**	**mean**	**Standard deviation**	**P.Value**	**P.Value**
ACT score in the beginning	10.95	3.70	---	11.15	4.02	---	0.871
ACT score in week 4	11.50	3.32	0.002	11.45	3.89	0.055	0.965
ACT score in week 8	12.15	3.01	0.001	11.55	3.87	0.163	0.588
ACT score in week 12	12.70	2.90	0.002	11.60	3.81	0.330	0.311

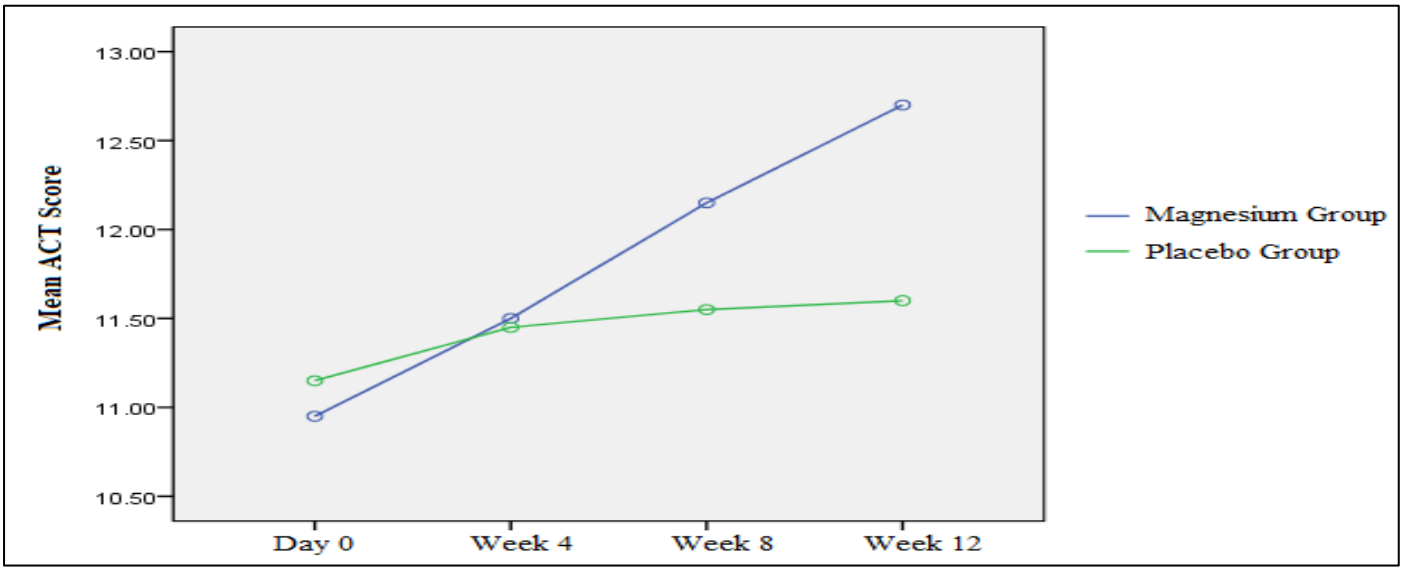

Fig 1 Comparison of ACT scores of asthmatic patients during the treatment process.

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The FEV1/FVC of all patients was less than 70 percent in the beginning of the research. According to table 3, the FEV1/FVC improvement rate in magnesium group did not have a significant difference in different weeks. Moreover, the FEV1/FVC improvement rate in magnesium group was not significantly higher than the placebo group (Chi Square test) in weeks 4 and 8, while it was significantly higher in week 12. Table 3 also compares the improvement rate base on FEV1 ratio of asthmatic patients after intervention. At the start, the frequencies of both group based on FEV1 ratio had no significant difference (Chi Square test). In both groups, FEV1 in 40% of participants was less than 60 percent and, in the rest, it was between 60-80 percent. According the bellow table, after intervention, while the FEV1 improvement rate in the magnesium group had no significant difference, the improvement rate in the magnesium group was significantly higher in weeks 8 and 12 in comparison with the placebo group. It was also higher in week but not significant. According to table 3, FVC improvement rate in the magnesium group had no significant difference in different weeks and it was not also significantly higher in comparison to the placebo group in weeks 4 and 12. However, it significantly increased in week 8 (Chi Square test).

Table 3 The Comparison of the Improvement rate in FEV1/FVC between Asthmatic Patients and Placebo Group

Time of measurement	**The frequency of the improvement in FEV1/FVC in the magnesium group**		**Comparison of different week in Magnesium group**	**The frequency of the improvement in FEV1/FVC in Placebo group**		**Comparison of different week in placebo group**	**Comparison Between the two groups**
	Number of participants	**percentage**	**P.Value**	**Number of participants**	**percentage**	**P.Value**	**P.Value**
Week 4	8	40%	---	3	15%	---	0.077
Week 8	7	35%	0.932	2	10%	0.854	0.058
Week 12	8	40%	0.945	2	10%	1	0.028
Time of measurement	**The frequency of the improvement in FEV1 in the magnesium group**		**Comparison of different week in Magnesium group**	**The frequency of the improvement in FEV1in Placebo group**		**Comparison of different week in placebo group**	**Comparison Between the two groups**
	Number of participants	**percentage**	**P.Value**	**Number of participants**	**percentage**	**P.Value**	**P.Value**
Week 4	8	40%	---	3	15%	---	0.077
Week 8	7	35%	0.932	1	5%	0.418	0.018
Week 12	8	40%	0.945	1	5%	0.999	0.008
Time of measurement	**The frequency of the improvement in FVC in the magnesium group**		**Comparison of different week in Magnesium group**	**The frequency of the improvement in FVC in Placebo group**		**Comparison of different week in placebo group**	**Comparison Between the two groups**
	Number of participants	**percentage**	**P.Value**	**Number of participants**	**percentage**	**P.Value**	**P.Value**
Week 4	2	10%	---	2	10%	---	1
Week 8	4	20	0.357	0	0%	0.563	0.035
Week 12	3	15	0.470	2	10%	0.421	0.633

Table 4 compares the improvement rate based on the Peak Flowmetry of the asthmatic patients after the intervention. According to the following table, after intervention, the improvement rate of peak flowmetry in the magnesium group had no significance difference in different weeks. However, it was higher in week 12 in comparison to other weeks. Moreover, the improvement rate of peak flowmetry in the magnesium group was not significantly higher than that in the placebo group (Chi square test). But, the frequency of improvement was significantly higher in the magnesium group than that in the placebo group.

Table 4 The Comparison of Improvement rate based on the Peak Flowmetry of the Asthmatic Patients.

Time of measurement	**The frequency of the improvement of peak flowmetry in the magnesium group**		**Comparison of different weeks in Magnesium group**	**The frequency of the improvement peak flowmetry in Placebo group**		**Comparison of different weeks in the placebo group**	**Comparison Between the two groups**
	Number of participants	**percentage**	**P.Value**	**Number of participants**	**percentage**	**P.Value**	**P.Value**

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Week 4	4	20%	---	3	15%	---	0.677
Week 8	6	30%	0.417	2	10%	0.854	0.114
Week 12	9	45%	0.151	4	20%	0.350	0.091

IV. DISCUSSION

Asthma is a common disease, which is getting more prevalent. Today, different studies have paid to the relationship between magnesium and asthma [38-42]. The present research aims to investigate the effects of oral magnesium on asthma control. 40 patients in 2 groups (each consisting of 20 participants) have studied, one group taking magnesium supplementation and the other placebo. 37 percent of participants were men and 63 percent of them women. At the start of the research, the disease severity for 60% of patients was mild and for 40% of them high. FEV1/FVC for all patients was less than 70 percent and the FEV1 for 40% of patients in the second group was less than 60 percent and for 60% of them was between 60-80 percent. After the magnesium supplements and placebo intervention, the FEV1/FVC improvement rate was measured in different weeks. The results showed that there was no significant difference in the magnesium group in different weeks. But the frequency of improvement for the magnesium group was significantly higher than that for the placebo group in week 12. In addition, the FEV1/FVC improvement rate in the magnesium group higher than that in the placebo group in weeks 4 and 8, though it was not significant. Moreover, the findings about FVC were the same and the improvement rate of patients taking magnesium was higher than the placebo group over time.

After the medication intervention, the improvement rate of peak flowmetery for the magnesium group in week 12 was higher than the previous weeks and the improvement rate in the magnesium group was also significantly higher than that in the placebo group. Therefore, the results show that the increase in duration of magnesium medication may gradually improve the asthma, although the improvement seems to be slow and takes time. The effects are possibly of the Antagonistic modulatory roles of magnesium and calcium and the smooth muscles expansion of brochi and T cells fixation and the stimulation of nitric oxide synthase [43-47].

The research conducted by Kazaks et all (2010) in America also studied the effects of oral magnesium supplementation on the respiratory airways and the life quality of asthmatic patients and its results showed that in those patients taking magnesium supplementation the FEV1 increased gradually and their life quality improved progressively [48]. Then, the results were similar to the findings of the present research; however, Kazaks' research lasted 6.5 months. In the research conducted by Virani et all, findings also indicated that Oral magnesium supplementation was associated with Improved pulmonary function on the FEVI and FVC, decreased airway reactivity and wheezing, less frequent asthma flare ups, fewer outpatient visits, less use of inhaled corticosteroids, and decreased skin response to allergens. Adverse events were rare and most commonly included abdominal cramps and diarrhoea [55-59]. Gontijo-Amaral's studies in Brazil also showed that the asthmatic children taking magnesium supplementation experienced less attacks in comparison to the placebo group and needed to take less salbutamol [53]. In the research done by Britton et all in England, FEV1 of the asthmatic patients increased significantly after the daily intake of 100 ml of magnesium for 6 months and their PEFR also improved [54,60,61].

In the present research, according to the changes in the score of ACT questionnaire, the ACT score increased significantly in all weeks as to last four weeks ; while, it had no significance difference in different weeks in the placebo group. However, the difference between these two groups was more in week 12 as to the beginning of the research. ACT questionnaire was a standard mixed survey based on the patients' symptoms, their need to the intake of life-saving drugs such as salbutamol, the impacts of the disease on daily performance and the patient's evaluation of the asthma-control; higher scores represent more desirable asthma control [52, 51,62]. Thus, the intake of oral magnesium supplementation has improved patients' clinical condition in addition to their spirometeric parameters.

Magnesium has been long employed as a effective medication in the treatment of asthma attacks. But its consumption as a long-term treatment has been posed recently. Studies similar to the present research have emphasized on the effects of magnesium on the improvement of asthmatic symptoms. Nonetheless, these results are not thoroughly coincided, as Fogarty et al asserted that the intake of magnesium supplementation had no effects in the clinical improvement of asthmatic patients and FEC1 and FVC variables [55,63]. This shows that the subject requires to be studied more.

Nutrients, particularly micronutrients and minerals like magnesium have an important role in the performance of immune system; their deficiency can result in the malfunction of the immune system. The mechanism of the action of minerals like magnesium on the pulmonary performance is not completely clear; but, it probably functions through the adjustment of the smooth muscle contraction and the release of chemical intermediates by being calcium antagonist. In fact, this element, in competition with calcium, controls calcium release from the Sarcoplasmic reticulum on one side and reduces bronchospasm by expanding smooth muscle of Broncho on the other side; this eventually results in the effective control of asthma attacks [6,64,65]. Wei also showed that Mg-deficient laboratory animals have higher histamines plasma levels compared to allergens [56]. Therefore, magnesium can be regarded as an effective element in asthma control and its deficiency may be dangerous to health. Gililand, F.D investigated the effects of dietary magnesium, potassium, and sodium on children's lung function, the authors examined cross-sectional dietary data and pulmonary

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function test in children aged 11-19; just 14 percent of boys and 12 percent of girls had enough daily magnesium intake. Those with lower magnesium intake had lower forced expiratory flow or forced vital capacity [57,66]. Almoundi et al in their research in Saudi Arabia in 2001 studied the electrolytes level of asthmatic patients and observed that the most prevalent deficit in them is related to magnesium and phosphor [5]. Therefore, the consideration of magnesium plasma level, especially in asthmatic patients and their enough dietary magnesium intake is of great importance. However, it should be noted that, just like potassium, magnesium is an intracellular ion, so the measurement of its plasma level may not reflect the inside level of cells properly and patients with natural plasma level may have magnesium deficits to a great extent [58]. On the other side, the effects of beta agonists reduce magnesium plasma level.

Though, Magnesium is available and cheap, which makes it a valuable medicine in asthma control and treatment; If consumed properly, its side effects would be also very few.

V. CONCLUSIONS

- In general, the findings of the research indicate that oral magnesium supplementations are effective in the pulmonary performance improvement and the results of the spirometry parameters of moderate and sever asthmatic patients. Moreover, the magnesium intake improves reduces the clinical signs.
- The effects are possibly of the Antagonistic modulatory roles of magnesium and calcium and the smooth muscles expansion of brochi and T cells fixation and the stimulation of nitric oxide synthase.
- It is suggested that more studies be conducted on this element with bigger sample and also on its effects compared to other medicines.
- Additionally, more research can be done on the adverse effects of the medicine and its effect based on the blood magnesium plasma level.

➢ *Author Contributions:*

Conceptualization, Ali Sharifpour and Babak Mahmoudi; Formal analysis, payam Ali khiavi; Investigation, Milad Anoushe; Methodology, Babak Mahmoudi and Reza Mahmoudi; Project administration, Milad Anoushe; Software, Reza Mahmoudi; Supervision, payam Ali khiavi; Validation, Ali Sharifpour; Visualization, Milad Anoushe; Writing – original draft, Babak Mahmoudi and Milad Anoushe; Writing – review & editing, Babak Mahmoudi and Siavash Abedi.

➢ *Conflicts of Interest:*

The authors declare no conflict of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish the results.

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