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## Original Article

# Nebulization by Isotonic Magnesium Sulphate Solution with Salbutamol Provide Early and Better Response as Compared to Conventional Approach (Salbutamol Plus Normal Saline) in Acute Exacerbation of Asthma in Children.

T Akter[1], N Islam[2], MA Hoque[3], S Khanam[4], HA khan[5], BK Saha[6]

**Abstract:**

Asthma attacks are serious respiratory problem that can be lethal when not treated appropriately. Till today the main stay of therapy is short acting ß2-agonist. Unfortunately in acute asthma episodes this is not enough to relieve the bronchospasm and reduce dyspnea. The shortcoming of ß2-agonist therapy has resulted in the use of a variety of other treatment in the management of acute asthma. The use of magnesium sulphate is one of the recent treatment options. This study was done to compare the efficacy of nebulized salbutamol with magnesium sulphate versus salbutamol with normal saline in the treatment of acute exacerbation of asthma in children. This randomized controlled trial was carried out among 60 patients with acute exacerbation of bronchial asthma fulfilling the inclusion criteria, admitted in the department of Paediatrics, Mymensingh Medical College Hospital over a period of one year from January 2009 to December 2009. They were distributed randomly, 30 patients received nebulized salbutamol (0.15mg/kg; minimum dose 2.5mg) with 2.0 ml of isotonic magnesium sulphate solution and another 30 patients received the same dose of salbutamol with 2.0 ml of normal saline on 3 occasions at 20 minute intervals. With single dose of nebulization in the magnesium sulphate with salbutamol group, by 20 minute almost all 26 (86.7%) patients achieved at least 60% of predicted PEFR. Within 20 minute from control group none could achieve 60% of predicted PEFR. After second dose of nebulization control group started achieving 60% of predicted value. Regarding response criteria, with second dose of nebulization, at 40 minute 16 (53.3%) patient from magnesium sulphate with salbutamol group showed good response (PEFR>70% predicted). But within the first 40 minutes, none could show good response in control group. With 3rd dose of nebulization all from magnesium sulphate group showed good response but even at 60 minute, 5 (16.7%) patients in control group failed to be included as good responder. In conclusion, nebulization by isotonic magnesium sulphate solution with salbutamol provide early and better response as compared to conventional approach (salbutamol plus normal saline) in acute exacerbation of asthma in children.

**Key words:** Asthma, Magnesium sulphate, Salbutamol, PEFR

## Introduction:

Asthma is an important chronic disorder of the airways with significant morbidity and mortality. Around 300 million people in the world currently have asthma. It is estimated that there may be additional 100 million people with asthma by 2015[1]. During the last few decades, the prevalence of asthma in childhood has increased worldwide.

1) Dr. Tahmina Akter, MD (Paediatrics) Asst. Prof. of Paediatrics, Diabetic Association Medical College, Faridpur.

2) Professor Dr. Md. Nazrul Islam, FCPS (Paediatrics), Prof of Paediatrics, Community Based Medical College, Mymensingh.

3) Dr. Mohammad Azizul Hoque, FCPS (Paediatrics), Associate Professor of paediatrics, Mymensingh Medical College, Mymensingh.

4) Dr. Suraya Khanam, DGO, Asst Prof. of Gynae and Obstetrics, Diabetic Association Medical College, Faridpur.

5) Dr. Husnea Ara Khan, FCPS (Paediatrics), Junior Consultant of paediatrics, Chokoria, Cox's Bazar.

6) Dr. Bijoy Kumar Saha, MBBS, Registrar, Dept. Of paediatrics, Diabetic Association Medical College, Faridpur.

**Address of correspondence :**
Dr. Tahmina Akter, MD (Paediatrics) Asst. Prof. of Paediatrics, Diabetic Association Medical College, Faridpur.
Mobile: +88-01710989403. Email: shelly21stssmc@gmail.com

Asthma is the commonest cause of hospitalization other than infection, in children under 15 years in USA. Children with asthma commonly seek care for acute exacerbation in the Emergency Department (ED). Urban children often use the ED as a primary source of asthma care. Children aged 0-17 years had over 867,000 ED visits and an ED visit rate was 124 per 10,000[2]. In Bangladesh about 7 million people (5.2% of the population) are suffering from current asthma and 7.4% of the pediatric population in our country is suffering from asthma[1].

Currently cornerstone of therapy for acute exacerbation of asthma is rapid reversal of airway obstruction. The main stay of therapy is short acting ß2-agonist therapy. Despite the effectiveness of ß2-agonists, as many as 30% of patients presenting to the emergency department fail to respond adequately to these medications and require hospital admission[3]. In addition to ß2-agonist inhalation, anticholinergic drugs act as antibronchoconstrictors by blocking muscarinic receptors, which cause tightening of smooth muscle in

and around airways. But the onset of action of anticholinergic drugs is slow with maximum effect after approximately 30-60 minutes[1]. Xanthine derivatives are bronchodilator medicines that open airways by relaxing the muscles in and around the airways that tighten during asthma episodes and facilitate diaphragmatic movement during inspiration. They also have some anti inflammatory properties[1]. Xanthine derivatives have narrow therapeutic range, individual differences in metabolic clearance and are associated with adverse effects at usual therapeutic doses. There is minimal evidence for added benefit to optimal doses of inhaled ß2-agonist. They are not generally recommended for exacerbation of asthma[4].

All these facts stress the need for the emergency based intervention. Therefore, an agent that could help reverse bronchoconstriction early in the attack would be of great benefit. An efficient asthma adjunct is needed to help bridge the time to onset of corticosteroid therapy effects specially in subpopulation of patient with acute asthma. This ideal drug should be fast acting, safe and effective.

In patients with acute asthma exacerbation, the use of isotonic magnesium as a vehicle for nebulized salbutamol produced a significantly greater increase in peak expiratory flow compared with salbutamol in saline. The more severe the baseline obstruction the greater the response to the combined magnesium sulphate and salbutamol, which supports the observation that magnesium is particularly effective in acute exacerbation of asthma[5].

Most of the studies[6] measured 1st outcome at 10 minute after completion of the nebulization. Some study also measured 1st outcome at least 30 minute after completion of nebulization. In some study, it is found that magnesium sulphate has better response as compared to normal saline. But no known study completed recommended schedule of 3 doses of nebulization.

This study was done to compare the efficacy of nebulized salbutamol with magnesium sulphate versus salbutamol with normal saline in the treatment of acute exacerbation of asthma in children.

**Materials and Methods:**

This randomized controlled trial was carried out among 60 patients with acute exacerbation of bronchial asthma admitted in the department of Paediatrics, Mymensingh Medical College Hospital over a period of one year from January 2009 to December 2009. Children of either sex with acute exacerbation of asthma, age ranging from 6 to 12 years and those who were capable of measuring PEFR were included and any evidence of respiratory tract infection or suppurative lung disease, any history or evidence of cardiac, renal or hepatic dysfunction, use of short acting bronchodilators within 8 hours or long acting bronchodilators within 24 hours & use of steroid within seven days were excluded from the study. A total 60 patients were taken as sample size. Thirty patients were in nebulized magnesium sulphate with salbutamol group and the rest 30 were in nebulized salbutamol with normal saline i.e., control group.

**Study procedure:**

Preparation of isotonic magnesium sulphate solution.

Magnesium sulphate solution 7.5% (w/v) is isotonic (286 mOsm).

In Inj G-MAG SULPH®; 2.47g magnesium sulphate contained in 5 ml. So 7.5g magnesium sulphate contained in 5×7.5 ml/2.47 =15.18 ml (approximately).

In a sterile amber coloured glass bottle, 15.18 ml of inj G-MAG SULPH® taken and then sterile distilled water added to make the total volume 100 ml. This isotonic magnesium sulphate solution.

**Preparation for randomized controlled trial:**

Step-1: 60 sets of identical eppendorf tube (each set containing 3 eppendorf tube) were taken and labeled serially from 1 to 60. In any set all the eppendorf tube had the same label number.

Step-2: Every odd number of eppendorf tubes are filled with isotonic magnesium sulphate solution and every even number of eppendorf tube are filled with normal saline solution. In any set each eppendorf contain 2.0 ml of same fluid (either isotonic magnesium sulphate or normal saline solution).

**Clinical procedure:**

Step-1: As any patient presented to the Paediatric Department of Mymensingh Medical College Hospital indoor with respiratory distress, he/she was assessed with a view to establish the diagnosis and severity of exacerbation of asthma.

Step-2: On the basis of inclusion and exclusion criteria, patients were enrolled in the study.

Step-3: Clinical examinations of the patients were done with regards to vital signs of acute attack as well as the chest findings as per requirements of the study.

Step-4: Questionnaire-cum-data sheet filled in.

Step-5: Objective measurement of airway obstruction was recorded with a peak flow meter. The procedure of using the peak flow meter was demonstrated to the patient.

**Data analysis:**

Data were analyzed manually and by computer. Results were expressed as mean ±SD. The primary end point was relative changes in peak expiratory flow rate.
Initially the base lines between the two groups were compared. Then the improvement in peak flow, respiratory rate. Pulse rate and $SaO_2$ were compared at 20, 40 and 60 minutes from the start point.
Most of the analyses were done by SPSS 14.0 for Windows (Statistical package for social science) software. Unpaired student's "t" test was used to compare means between two groups. Chi-square analysis was done to compare distribution of age, sex, family history of asthma, history of smoking, medication and presenting symptoms and signs.

Confidence interval was set at 95% level. Results were considered to statistically significant at P value <0.05. When <0.001, P value was considered as highly significant.

**Observation and Results:**

In the isotonic magnesium sulphate with salbutamol group 14 patients were female and 16 patients were male, On the other hand in the control (salbutamol) group 12 patients were female and 18 patients were male.

**Table I:** Baseline characteristics of patients.

| Parameters | Magnesium sulphate with salbutamol group (n=30), mean ±SD | Salbutamol (control) group (n=30) mean ±SD | P value |
|---|---|---|---|
| Age (years) | 10.06±1.70 | 9.40±1.65 | >0.10ns |
| Height (inch) | 51.17±2.46 | 50.63±2.83 | >0.10ns |
| Weight (kg) | 26.40±3.02 | 25.93±4.79 | >0.10ns |
| Duration of asthma (years) | 2.23±1.19 | 2.10±0.88 | >0.10ns |

Table I shows the baseline characteristics of patients of two groups. Age of the patients in magnesium sulphate with salbutamol group was 10.06±1.70 years whereas in salbutamol (control) group it was 9.40±1.65 years. In magnesium sulphate with salbutamol and control group height was 51.17±2.46 inches and 50.63±2.83 inches respectively. Weight of the patients in magnesium sulphate with salbutamol and control group was 26.40±3.02kg and 25.93±4.79kg respectively.

The duration of asthma was 2.23±1.19 years in the magnesium sulphate with salbutamol group and 2.10±0.88 years in the control group. In all cases the differences between the groups were not statistically significant.

**Table II:** Presenting symptoms and sign

| Parameters | Magnesium sulphate with salbutamol group (n=30) | | Salbutamol (Control) group (no=30) | | P value |
|---|---|---|---|---|---|
| | No. | % | No. | % | |
| **Symptoms** | | | | | |
| Breathlessness during | | | | | |
| Talking | 28 | 93.3 | 27 | 90 | |
| Resting | 2 | 6.7 | 3 | 10 | >.010ns |
| Physical exhaustion | | | | | |
| Yes | 2 | 6.7 | 1 | 3.3 | |
| No | 28 | 93.3 | 29 | 96.7 | >.010ns |
| Talks in | | | | | |
| Phrases | 27 | 90 | 28 | 93.3 | |
| Words | 3 | 10 | 2 | 6.7 | >.010ns |
| **Signs** | | | | | |
| Wheeze | | | | | |
| Loud | 26 | 86.7 | 25 | 83.3 | |
| Very loud | 4 | 13.3 | 5 | 16.7 | >.010ns |
| Use of accessory muscle | | | | | |
| No | 2 | 6.7 | 3 | 10 | |
| Yes | 27 | 90 | 27 | 90 | .010ns |
| Prominent | 1 | 3.3 | 0 | 0 | |
| Pulse (per minute) | | | | | |
| 100-160 | 30 | 100 | 30 | 100 | a |
| PEFR (%) | | | | | |
| 40-60 | 30 | 100 | 30 | 100 | a |
| $SaO^2$ | | | | | |
| 94%-90% | 28 | 93.3 | 29 | 96.7 | |
| <90% | 1 | 6.7 | 1 | 3.3 | >.010ns |

Table II shows that all cases pulse rate was within 100-160 per minute and PEFR was 40-60 percent of predicted value. In magnesium sulphate with salbutamol and control group 28 and 27 patients respectively were breathless during talking while 2 and 3 patients were breathless during resting.

Only 2 patients from magnesium sulphate with salbutamol group and 1 from control group were

exhausted during presentation. Twenty seven patients talked in phrases and 3 in words in the magnesium sulphate plus salbutamol group whereas 28 patients talked in phrases and 2 in words in the control group.

In the magnesium sulphate with salbutamol group. Loud and very loud wheeze present in 26 and 4 patients respectively while in the control group they were found in 25 and 5 patients.

The differences were not statistically significant in all the parameters in both the group.

**Table III:** PEFR (L/min) status at different times.

| Parameters | Magnesium sulphate with salbutamol group (n=30) Mean±SD | Salbutamol (control) Group(n=30) Mean±SD | P value |
|---|---|---|---|
| Predicted | 253.73±32.01 | 247.17±42.08 | >0.10ns |
| 0 min/base line | 125.53±15.13 | 120.00±20.72 | >0.10ns |
| Mean percent of predicted 20 min/base line | 49.47±3.52 | 48.55±3.41 | >0.10ns |
| Mean percent change from 0 min | 159.94±22.30 | 141.96±25.59 | <0.01* |
| Mean percent of predicted 40 min/base line | 27.41±7.25 | 18.29±6.36 | <0.001* |
| Mean percent change from 0 min | 63.03±1.74 | 57.44±1.36 | <0.001* |
| Mean percent of predicted 60 min/base line | 178.24±23.64 | 156.39±27.42 | <0.01* |
| Mean percent change from 0 min | 41.99±9.55 | 30.32±8.36 | <0.001* |
| Mean percent of predicted | 70.25±1.44 | 63.27±1.39 | <0.001* |
| | 194.82±25.32 | 175.69±32.42 | <0.01* |
| | 55.19±8.33 | 46.41±7.59 | <0.001* |
| | 76.78±1.84 | 71.08±1.56 | <0.001* |

Table III shows baseline (0 minute) peak expiratory flow rate (L/min) between the groups both in absolute value and percent of predicted were similar. Absent value mean±SD for magnesium sulphate with salbutamol group was 125.73±15.13 L/min and for control group was 120.00±20.72 L/min. P value was reached by Unpaired students' 't' test and was >0.01 which was not significant. Mean of percent predicted value for magnesium sulphate with salbutamol and control group 49.47±3.52 and 48.55±3.41 respectively and the differences were also non significant <P value >0.10)

At 20 minute, mean expiratory flow rate, mean percent change from 0 minute (baseline) and mean percent of predicted value for magnesium sulphate with salbutamol and control groups respectively were 159.94 ±22.30 and141.96±25.59 (P value <0.01); 27.41±7.25 and 18.29±6.36 (P value <0.001); 63.03±1.74 and 57.44±1.36 (P value <0.001) respectively. So at 20 minute, there are significant differences between the groups regarding peak flow rate (absolute value), percent improvement from base line and improvement in percent predicted value. Similar type of results were founds up to 60 minute of the study period.

**Table IV:** Comparison of patients achieving at least 60% of predicted value

| Parameters | Magnesium sulphate with salbutamol group (n=30) | | Salbutamol (Control) group (no=30) | | P value |
|---|---|---|---|---|---|
| | No. | % | No. | % | |
| At 0 min PEFR | | | | | |
| ≥ 60% predicted | 0 | 0 | 0 | 0 | a |
| < 60% predicted | 30 | 100 | 30 | 100 | |
| At 20 min PEFR | | | | | |
| ≥ 60% predicted | 26 | 86.7 | 0 | 0 | <0.001* |
| < 60% predicted | 4 | 13.3 | 30 | 100 | |
| At 40 min PEFR | | | | | |
| ≥ 60% predicted | 30 | 100 | 28 | 93.3 | >0.1ns |
| < 60% predicted | 0 | 0 | 2 | 6.7 | |
| At 60 min PEFR | | | | | |
| ≥ 60% predicted | 30 | 100 | 30 | 100 | |
| < 60% predicted | 0 | 0 | 0 | 0 | A |

Table IV shows, at presentation, all the patient had PEFR <60% predicted value. In magnesium sulphate with salbutamol group at 20 minute from the start point 26 patients achieved at least 60% of predicted PEFR. So with single dose of nebulization almost all children (26 out of 30) achieved at least 60% predicted PEFR in magnesium sulphate with salbutamol group. Within this 20 minute, in the control group none could achieve PEFR at least 60% of the predicted value.

Immediately after recording data as per schedule, second dose of nebulization done at 20 minute from start point. After another 20 minute at 40 minute from the start point 30 and 28 patient from magnesium sulphate with salbutamol and control group respectively achieved at least 60% of predicted value. At 60 minute all patient from both the group achieved PEFR at least 60% predicted.

**Table V:** Comparison of responses at different times

| Parameters | Magnesium sulphate with salbutamol group (n=30) | | Salbutamol (Control) group (no=30) | | P value |
|---|---|---|---|---|---|
| | No. | % | No. | % | |
| At 20 min PEFR | | | | | |
| Good response | 0 | 0 | 0 | 0 | |
| Incomplete response | 30 | 100 | 30 | 100 | a |
| Poor response | 0 | 0 | 0 | 0 | |
| At 40 min PEFR | | | | | |
| Good response | 16 | 53.3 | 0 | 0 | |
| Incomplete response | 14 | 47.7 | 30 | 100 | |
| Poor response | 0 | 0 | 0 | 0 | <0.001* |
| At 60 min PEFR | | | | | |
| Good response | 30 | 100 | 25 | 83.3 | |
| Incomplete response | 0 | 0 | 5 | 16.7 | |
| Poor response | 0 | 0 | 0 | 0 | <0.05* |

Good response : PEFR ≥ 70% of predicted value.
Incomplete response : PEFR 50% to < 70% of predicted value
Poor response : PEFR < 50% of predicted value

Table V shows that within 20 minutes, none could show the good response. Second dose of nebulization done at 20 minute after that at 40 minutes 16 (53.3%) patients in the magnesium sulphate with salbutamol group showed good response. Despite of using two doses of nebulization, within this 1st 40 minutes time from control group none could show good response (PEFR ≥70% of predicted). Immediately after recording data at 40 minutes 3rd dose of nebulization done. At 60 minute, 30 (100%) patient from magnesium sulphate with salbutamol group showed good response and 5 (16.7%) patient from the control group failed to show good response.

**Table VI:** Comparison of outcome at different times

| Parameters | | PEFR% predicted | Respiratory rate/min | Pulse rate/min | $SaO_2$ |
|---|---|---|---|---|---|
| | Group A | 49.47±3.52 | 34.33±1.58 | 123.53±4.38 | 90.83±1.12 |
| 0 min | Group B | 48.55±3.41 | 34.93±1.34 | 126.50±4.57 | 90.70±0.95 |
| | P value | >0.10ns | >0.05ns | >0.10ns | >0.05ns |
| | Group A | 63.03±1.74 | 28.63±2.22 | 104.50±5.32 | 92.83±1.05 |
| 20 min | Group B | 57.44±1.36 | 30.13±1.36 | 106.77±5.76 | 91.83±o.91 |
| | P value | <0.001* | <0.50* | >0.10ns | >0.05ns |
| | Group A | 70.25±1.03 | 24.93±1.72 | 94.07±4.75 | 94.77±0.90 |
| 40 min | Group B | 63.27±1.39 | 25.60±1.16 | 95.63±5.83 | 93.87±0.97 |
| | P value | <0.001* | <0.01* | >0.05ns | <0.05* |
| | Group A | 76.78±1.84 | 22.93±1.66 | 86.63±4.12 | 95.73±0.91 |
| 60 min | Group B | 71.08±1.54 | 23.93±0.83 | 89.27±5.42 | 95.80±0.85 |
| | P value | <0.001* | <0.001* | <0.001* | <0.05* |

Group A: Treated with magnesium sulphate plus salbutamol, Group B: Treated with salbutamol (control group)

Table VI show in addition to PEFR, respiratory rate, pulse rate and $SaO_2$ were also recorded at 0, 20, 40, and 60 minute. At 0 minute regarding all the parameters, differences between two groups were not significant. From 20 to 60 minute, differences of mean PEFR percent of predicted were always significant between the groups. (P value <0.001).

Respiratory rate at 0 minute was similar in both groups and from 20 up to 60 minute, respiratory improvement were significantly different. Pulse rate differences were not statistically significant up to 40 minutes. Only 2 patient (1 in magnesium sulphate with salbutamol group and 1 in control group) had $SaO_2$ 89% (within <90% range) at presentation, $SaO_2$ was ≥90% in all cases. Mean oxygen saturation at presentation was not significantly different. But from 20 minute up to 60 minute, improvement in mean $SaO_2$ was significantly different and magnesium sulphate with salbutamol group showed superiority.

**Discussion:**

This study revealed that combining nebulized isotonic magnesium sulphate with salbutamol results in early and better response in peak flow as compared with the standard approach (salbutamol plus normal saline) for nebulization in the initial treatment of acute exacerbation of asthma in children. The effect was evident at 20 minute and maintained up to 60 minute from the start point. This finding is consistent with that of Mollick (2003).

PEFR expressed as percentage predicted value eliminated gender, age. Weight and height bias and mean percent improvement in PEFR from baseline (0 minute) eliminated the bias introduced by difference in the degree of initial airflow obstruction. Mean percent of predicted PEFR detected in both group at 0, 20, 40 and 60 minutes. Results in both groups at base line (0 minute) were similar but from 20 minute up to 60 minute, the values were significantly different. Mean percent improvement in PEFR from baseline was always significantly different from 20 up to 60 minutes and magnesium sulphate with salbutamol group (Table III) showed superiority which is also consistent with findings of Naninni et al, (2000).

In this study, in the magnesium sulphate with salbutamol group at 20 minute from the start point 26 out of 30 patients achieved at least 60% of predicted PEFR. Following 1st dose of nebulization at 0 minute, within this 1st 20 minute from the control (salbutamol) group none could achieve PEFR at least 60% of the predicted value. Second dose of nebulization done at 20 minute and after another 20 minute from start point 30 (100%) and 28 (93.3%) patient from magnesium sulphate with salbutamol group and control group respectively achieved at least 60% of predicted value. From 60 minutes all patient from both the group achieved PEFR at least 60% predicted. In acute exacerbation of asthma, to reduce likelihood of relapse and hospitalization rate, achieving as rapidly as possible safe value for the percentage predicted peak flow about 60% is needed which is suggested as the cut off point between discharge from emergency department and admission into the hospital6. According to GINA (2005), patient with post treatment lung function (FEVi/PEF) in the range of 40%-60% of predicted value can potentially be discharged, assuming adequate follow up is available in the community and compliance is assured. Patients with objective evidence of lung function 60% predicted or greater can usually be discharged[7].

20 minute after 2nd dose of nebulization at 40 minute only 16 (53.3%) patients in the magnesium sulphate with salbutamol group showed good response (PEFR ≥70% predicted). Despite of using two doses of nebulization, within this 1st 40 minutes from control group none could show good response. With three doses of nebulization, at 60 minute, 30 (100%) patients from magnesium sulphate with salbutamol group and 25 (83.3%) patient in the control group showed good response. Finally 5 (16.6%) patient in the control group failed to be included as good responder (Table V). This finding consistent with Haqq et al, (2006)[8].

In the present study, all patient of magnesium sulphate with salbutamol group achieved 70% PEFR after 3 dose of nebulization. Naninni et al[6] conducted study with patient aged 18 years and over found significant benefit after single dose of nebulization with isotonic magnesium sulphate. But the effect is much better in the present study. Hughes et al., (2003) undertaken a double blind placebo controlled study and found significantly greater improvement in FEV1 with nebulized salbutamol plus isotonic magnesium sulphate solution than salbutamol plus normal saline. In that study 3 doses of nebulization were done and observations were made at 30 minute interval and the response was similar as 20 minute interval in the present study. Mollick 7 carried out prospective controlled study in adult population and also found the similar response after 10 minute of completion of treatment.

The current recommendation for initial treatment of acute asthma in 3 doses of nebulization at 20 minute interval for 1 hour but most of the studies[6,7] did not follow.

Though intravenous magnesium sulphate can be used as an adjunct to conventional nebulization and other therapy but if nebulization of salbutamol with isotonic magnesium sulphate can exert the same effect, use of this combination nebulization may be convenient both for the physician and for the patient. So the nebulization magnesium sulphate is preferable to IV magnesium[9].

Acute exacerbation of asthma requires start of treatment even at home and in the protocol of home management of asthma, oxygen administration is not recommended[5]. Acute hypoxia has no effect on short acting ß2 agonist (salbutamol) induced bronchodilatation in patients with asthma[9]. Improvements in Oxygen saturation following bronchodilator administration documents the presence of relative preexisting hypoxia which is reversed to some degree with bronchodilators[10]. In our study, oxygen saturation also raised to safe value in all patients (Table VI).

Following current recommendation for initial treatment of acute exacerbation of asthma, In this study, nebulization was done as one dose every 20 minutes for 1 hour and found that patient gets comfort earlier if salbutamol nebulization done with isotonic magnesium sulphate solution.

**Conclusion:**

This study concludes that combining isotonic magnesium sulphate solution 2.0ml with salbutamol for nebulization results in early response and greater improvement in peak expiratory flow rate as compared with the salbutamol nebulization with normal saline in the initial treatment of acute exacerbation of asthma in children. Patient treated by nebulized isotonic magnesium sulphate solution with salbutamol quickly achieves a safe value for the percentage predicted peak flow and at the end of initial treatment shows good response.

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