NEBULIZED MAGNESIUM SULFATE VERSUS NEBULIZED BUDESONIDE IN TREATMENT OF ACUTE BRONCHIOLITIS

By

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ABSTRACT

Background: *Acute bronchiolitis is an acute inflammatory injury of the bronchioles that is usually caused by a viral infection (most commonly respiratory syncytial virus and human metapneumovirus). This condition may occur at any age with peak incidence between 2 and 6 months old. In the present study we aimed to assess the efficacy of nebulized magnesium sulfate versus inhaled budesonide in treatment of infants hospitalized with acute bronchiolitis.*

Patients and Methods: *The study was conducted on 60 infants with moderate to severe bronchiolitis. They were randomly assigned into three groups, group A treated with inhaled budesonide plus nebulized B-2 agonist and group B treated with nebulized magnesium sulfate plus B-2 agonist and group C (control group) treated with nebulized B-2 agonist alone, all the patients were subjected to a complete history and clinical examination, and were investigated with emphasis on CBC with differential, CRP, ABG and chest X-ray. Length of hospital stay and duration of manifestations were recorded.*

Results: *Our study showed that the three groups were comparable as regard sex and age (p-value 0.935, 0.985 respectively).There was insignificant differences between three groups as regard main complain, past history, family history of atopy and duration of illness (p –value 0.891, 0.934, 0.926, 0.998 respectively).There was insignificant differences between the three groups as regard respiratory rate on admission (p-value 0.864) but after treatment group B showed a significant improvement compared to the other two groups (p-value <0.001).There was insignificant differences between the three groups as regard heart rate on admission (p-value 0.952) but after treatment group B showed a significant improvement compared to the other two groups (p-value 0.001).Patients in group B had the higher improvement in O2 saturation after treatment (p-value <0.001), as well as the best improvement as regard respiratory distress after treatment compared to the other groups (p-value <0.001).*

Key word: *Nebulized Mg sulphate, Versus Nebulized Budesonide, in Treatment of Acute Bronchiolitis.*

INTRODUCTION

Bronchiolitis, a lower respiratory tract infection that primarily affects the small airways (bronchioles), is a common cause of illness and hospitalization in infants and young children **(Piedra et al., 2016)**. Bronchiolitis is an acute infectious disease of the lower respiratory tract that occurs primarily in the very young, most commonly infants between 2 and 6 months old. It's a clinical diagnosis based upon **(Mejias et al., 2013)**.

- Breathing difficulties
- Cough
- Decreased feeding
- Irritability
- Apneas in the very young
- Wheeze or crepitations on auscultation

It is usually due to a viral infection of the bronchioles. Respiratory syncytial virus (RSV) is the most common pathogen, causing 50-90% of cases. A combination of increased production of mucus, cell debris and edema produces narrowing and obstruction of small airways. It is the most common cause of hospitalization in infants of acute respiratory failure in pediatric intensive care units (PICUs) in the UK **(NICE Guideline, 2015)**.

Aims of the Work

To assess effectiveness of using nebulized magnesium sulfate in comparison with effectiveness of nebulized budesonide in the treatment of children suffering from acute bronchiolitis.

PATIENTS AND METHODS

This is an Interventional comparative controlled study.

Patients and study period:

The study included 60 infants in the period from December 2019 till July 2020 at Al Hussein and Bab El Sharia hospitals of Azhar University.

Inclusion criteria:

The study included 60 infants at age from 2 months to 24 month with symptoms and signs of acute bronchiolitis (according to Scottish intercollegiate guidelines network, 2006), with the following clinical features:

1. Poor feeding less than 50% of usual fluid intake in preceding

24 hours, lethargy, history of apnea.

2. Respiratory rate more than 70 per minute.
3. Presence of nasal flaring and/or grunting.
4. Severe chest wall recession and cyanosis.
5. On examination there are fine inspiratory crackles and/or high pitched expiratory wheeze.

Exclusion criteria

1. Other causes of wheezy chest (as bronchial asthma).
2. Patients aged above 2 years.
3. Cardiac causes of wheezy chest
4. Patients with GERD.
5. Patients with pneumonia or upper respiratory tract infection
6. Patients with congenital thoracic anomalies.

Ethical consideration:

- Written Parent consent for the study was obtained before the study.
- Approval of the local ethical committee in the pediatrics department, college and university were obtained before the study.
- The authors' declared no potential conflict of interest with respect to the research & publication of this article.
- All the data of the patient & results of the study are confidential & the patient has the right to keep it.
- The authors received no financial support for the research & publications of the article.

Methods:

All the patients were subjected to:

1. **Full history:** Including main complain, history of present illness (duration of illness) and past history (previous similar attacks) and family history of atopy.
2. **Complete physical examination:** Observation of general appearance including presence of cyanosis or pallor, work of breathing and vital signs (respiratory rate, heart rate) on time of admission and daily observation of clinical improvement or deterioration.
3. **Lab evaluation including:** CBC, CRP, chest x-ray, and ABG.

Lastly our study cases were divided into three groups by systemic random method:

Group A treated with nebulized budesonide 0.5 mg divided twice

daily plus nebulized B-2 agonist 0.2 mg/kg/dose every 6 hours.

Group B patients were treated with nebulized magnesium sulfate 40 mg/kg/dose plus nebulized B-2 agonist 0.2 mg/kg/dose every 6 hours.

Group C (control patients) were treated with nebulized B-2 agonist alone 0.2 mg/kg/dose every 6 hours.

Statistical analysis:

Data was subjected to computer assisted statistical analysis using SPSS package version 22. Categorical data was described as frequency and percentage and compared using Chi Square tests. Numerical data was described as mean and standard deviation and compared using t test.

Non parametric data was described as median and range. Numerical associations were tested using Pearson's correlations and potential risk factors were tested using sensitivity, specificity and Odd ratio. P value less than 0.05 was considered significant.

RESULTS

Table (1): Comparison between the three groups regarding age and sex

	Group A (n = 20)		Group B (n = 20)		Control (n = 20)		Test of Sig.	p
	No.	%	No.	%	No.	%		
Sex								
Male	11	55.0	10	50.0	10	50.0	X^2=0.133	0.935
Female	9	45.0	10	50.0	10	50.0		
Male/Female ratio	1.2:1		1:1		1:1			
Age (months)								
5 - 10	6	30.0	5	25.0	6	30.0	X^2=0.827	0.985
11 - 20	10	50.0	10	50.0	11	55.0		
20- 24	4	20.0	5	25.0	3	15.0		
Mean ± SD.	14.5 ± 5.64		14.65 ± 5.51		14.45 ± 5.26		$_X^2$=0.030	0.985

This table showed that there was insignificant difference between the three studied groups regarding age and sex.

Table (2): Comparison between the three studied groups regarding clinical data on admission

	Group A (n= 20)		Group B (n = 20)		Control (n = 20)		Test of Sig.	p
	No.	%	No.	%	No.	%		
Main Complain								
Breathing difficulties	14	70.0	12	60.0	11	55.0	X^2=1.455	0.891
Cough	4	20.0	6	30.0	7	35.0		
Cyanosis	2	10.0	2	10.0	2	10.0		
Past History of bronchiolitis	11	55.0	12	60.0	12	60.0	X^2=0.137	0.934
Family History of atopy	7	35.0	6	30.0	6	30.0	$_X{}^2$=0.154	0.926
Duration of Illness (hrs.) Mean ± SD.	16.4±8.18		16.35±8.20		16.35±8.20		X^2=0.004	0.998

Table 2 showed that there was insignificant difference bet. The three studied groups regarding clinical data on admission.

Table (3): Comparison between the three studied groups as regard respiratory rate before and after treatment

Respiratory Rate	Group A (n = 20)	Group B (n = 20)	Control (n = 20)	F	p
On Admission					
Mean ± SD.	75.95 ± 3.73	75.8 ± 3.55	75.35 ± 3.67	0.146	0.864
After treatment: at6hr					
Mean ± SD.	75.75 ± 2.77	74.85 ± 3.23	74.85 ± 3.23	0.567	0.570
At 24hrs					
Mean ± SD.	75.50 ± 4.35	67.25 ± 1.62	74.85 ± 3.23	39.497*	<0.001*
At 48hrs					
Mean ± SD.	75.85 ± 3.41	58.6 ± 3.83	75.35 ± 3.67	145.378*	<0.001*
Sig. bet. Periods	0.818	<0.001*	1.000		

*P1: correlation regarding respiratory rate before and after treatment in group A *P2: correlation regarding respiratory rate before and after treatment in group B *P3: correlation regarding respiratory rate before and after treatment in group C.

Table 3 showed that there was insignificant differences between three groups as regard respiratory rate on admission (p-value 0.864) and after 6 hours of treatment (p-value 0.570) but after 24 hours and 48 hours of treatment there was significant differences between the three groups (p-value <0.001) with significant improvement of RR by time in the three groups.

Table (4): Comparison between the three studied groups regarding heart rate before and after treatment

Heart Rate	Group A (n = 20)	Group B (n = 20)	Control (n = 20)	F	p
On Admission Mean ± SD.	153.35 ± 7.13	152.75 ± 6.92	152.75 ± 6.92	0.049	0.952
After treatment At 6 hr Mean ± SD.	149.90 ± 8.49	147.95 ± 6.65	149.90 ± 8.49	0.404	0.952
At 24hrs Mean ± SD.	152.90 ± 10.01	143.55 ± 7.66	145.65 ± 8.03	6.462*	0.003*
At 48hrs Mean ± SD.	152.35 ± 6.96	142.7 ± 7.63	146.85 ± 7.7	8.471*	0.001*
Sig. bet. Periods	0.096	<0.001*	<0.001*		

*P1: correlation regarding heart rate before and after treatment in group A*P2: correlation regarding heart rate before and after treatment in group B *P3: correlation regarding heart rate before and after treatment in group C.

Table 4 showed that there was insignificant differences between the three groups as regard heart rate on admission (p-value 0.952) and after 6 hours of treatment (p-value 0.952) but after 24 hours and 48 hours of treatment there was significant differences between the three groups regarding heart rate (p-value 0.003, 0.001 respectively), with significant differences in time in the three groups.

Table (5): Comparison between the three studied groups regarding O2 saturation before and after treatment

O_2 saturation	**Group A (n = 20)**	**Group B (n = 20)**	**Control (n = 20)**	**F**	**p**
On admission Mean ± SD.	91.05 ± 2.35	93.15 ± 2.70	93.15 ± 2.70	4.386*	0.017*
After treatment **At 6hrs** Mean ± SD.	89.90 ± 3.11	90.95 ± 3.25	90.10 ± 2.97	0.641	0.530
At 24hrs Mean ± SD.	91.05 ± 2.63	93.10 ± 2.94	90.20 ± 3.21	*5.171	0.009*
At 48hrs Mean ± SD.	90.95 ± 1.82	95.10 ± 1.65	93.30 ± 2.49	21.194*	<0.001*
Sig. bet. Periods	0.748	0.001*	0.267		

*P1: relation between group A and o2 saturation before and after treatment *P2: relation between group b and o2 saturation before and after treatment *P3: relation between group c and o2 saturation before and after treatment

Table 5 showed that mean value of O2 saturation in group A, B, and control group, which revealed that patients in group B had the higher improvement in O2 saturation after 24 hours, and 48 hours of treatment with significant differences between three groups (p-value 0.009,<0.001 respectively), with significant difference in time in the three groups.

Table (6): Comparison between the three studied groups as regard the degree of RD before and after treatment

Degree of RD	Group A (n = 20)		Group B (n = 20)		Control (n = 20)		x^2	p
	No.	%	No.	%	No.	%		
On Admission								
G2	12	60.0	12	60.0	12	60.0	0.000	1.000
G3	8	40.0	8	40.0	8	40.0		
After treatment								
After 6hr								
G2	12	60.0	12	60.0	12	60.0	0.000	1.000
G3	8	40.0	8	40.0	8	40.0		
After 24hrs								
G1	1	5.0	5	25.0	0	0.0		
G2	11	55.0	11	65.0	12	60.0	7.386	0.098
G3	8	40.0	4	20.0	8	40.0		
After 48hrs								
G1	2	10.0	7	35.0	0	0.0	17.632	<0.001*
G2	11	55.0	13	65.0	12	60.0		
G3	7	35.0	0	0.0	8	40.0		
Sig. bet. Periods	0.317		0.003*		1.000			

*P1: correlation in group A regarding degree of RD before and after treatment *P2: correlation in group B regarding degree of RD before and after treatment *P3: correlation in group C regarding degree of RD before and after treatment, G1: tachypnea, G2: tachypnea and retractions, G3: tachypnea, retractions & grunting.

Table 6 showed that group B had the best improvement as regard respiratory distress after 48 hours of treatment compared to group A and control group with significant differences between the three groups (p-value <0.001).

Table (7): Comparison between the three studied groups regarding chest radiological findings on admission

Chest X –Ray	Group A (n = 20)		Group B (n = 20)		Control (n = 20)		X^2	P
	No.	%	No.	%	No.	%		
Normal	0	0.0	0	0.0	1	5.0	4.194	0.722
Consolidation	5	25.0	3	15.0	4	20.0		
Atelectasis	3	15.0	4	20.0	6	30.0		
Hyperinflation	12	60.0	13	65.0	9	45.0		

Table 7 showed that there was insignificant difference bet. The three groups regarding radiological findings.

Table (8): Comparison between the three studied groups regarding the length of hospital stay

	Group A (n = 20)	**Group B (n = 20)**	**Control (n = 20)**	**F**	**p**
Lengths of Hospital stay (hrs.) Mean ± SD.	77.9 ± 9.3	68.0 ± 10.01	77.7 ± 8.78	7.290*	0.002*
Sig. bet. Grps.	p1= 0.001*, p2= 0.946, p3= 0.002*				

Table 8 showed that there was a significant difference between three groups as regard length of hospital stay (p-value 0.002).

DISCUSSION

Acute bronchiolitis is one of the most common diseases of childhood, characterized by inflammation, edema, necrosis of small airways and bronchospasm. The typical symptoms are cough, rhinitis, tachypnea, wheezing and respiratory distress. The main principles of treatment are supportive including follow up of oxygen saturation, fluid balance and nutrition status. There are diverse variations in diagnosis and treatment of acute bronchiolitis in children. Also there is no consensus about the fluid therapy in acute bronchiolitis **(Yildirim et al., 2016)**.

The role of bronchodilators in the treatment of bronchiolitis has been the subject of many studies. In general, no single treatment modality has proven effective in controlling the disease. Magnesium is an important cofactor in many enzymatic reactions and is linked to cellular homeostasis **(Francis et al., 2010)**.

Studies demonstrated that magnesium inhibits the contraction of smooth muscle, acetylcholine release, and histamine release. Thus, both intravenous and nebulized magnesium sulfate has become a treatment option in acute asthma in adults and children **(Powell et al., 2012)**.

The present study aimed to assess the efficacy of nebulized magnesium sulfate versus inhaled budesonide in treatment of infants

hospitalized with acute bronchiolitis. The study comprised 60 infants with moderate to severe bronchiolitis admitted into the Al Azhar University Hospitals.

In our work 30% of patients in group A and C were aged 5 to 10 months old age and 25% of group B, while 50 % of both groups A and B were aged 10 to 20 months old age and 55% of group C. Only 20 %, 25% and 15% of groups A, B and C respectively were aged over 20 months.

In a study on nebulized Magnesium Sulfate in acute bronchiolitis by **Modaresi et al.,** which comprised 140 infants, they included younger patients with mean age of 5.2 months in group 1 and 4.8 months in group 2. The M/F ratio in group 1 was 34/26 and in group 2 38/22 **(Modaresi et al., 2015)**.

In the present study we found that the main complain in the studied groups was breathing difficulties which accounted to 70%,60%, 55% in group A, B, and control group respectively, followed by cough and cyanosis. 55% of patients involved in group A had positive past history, while 60% of both groups B and control had positive past history of similar illness.

In the present study we found that the mean respiratory rate on admission in group A, B, and control group was 75.9, 75.8, and 75.3 C\min respectively. The mean respiratory rate in group A, B, and control group after admission was 75.8, 58.6, and 75.3 C\min respectively.

There was insignificant differences between three groups as regard respiratory rate on admission (p-value 0.864) and after 6 hours of treatment (p-value 0.570) but after 24 hours and 48 hours of treatment group B showed a significant improvement with significant differences between the three groups as regard respiratory rate after treatment (p-value <0.001). Moreover we found that group B had the best improvement as regard respiratory distress after treatment with significant differences between the three groups (p-value <0.001).

Modaresi et al., agree with our result as they found that respiratory rate before treatment in both Magnesium sulfate group and the other group was 66c\m, also the groups studied had no significant difference in RDAI score on the first day of admission, However the RDAI score was significantly lower in magnesium sulfate plus epinephrine group on second and

third day after admission (P 0.01) **(Modaresi et al., 2015)**.

In the present study we found that that O_2 saturation on admission on group A, B, and control was 91.05%, 93.15%, 93.15% respectively.

The O_2 saturation after treatment in group A, B, and control was 90.95 %, 95.10 %, 93.30 % respectively, which reveals that patients in group B had the higher improvement in O2 saturation after 24 hours and 48 hours of treatment. The differences between three groups was significant (p-value 0.009, <0.001) respectively.

Regarding response criteria, **Daengsuwan and Watanatham (2017)** reported that with 2nd dose of nebulization with magnesium sulfate plus salbutamol, at 30 and at 40 minute 30.0% and 56.7% of patients respectively from magnesium sulfate with salbutamol group showed good response (PEFR > 70% predicted). But within this first 40 minutes time, none of control group could show good response. With 3rd dose of nebulization all patients from magnesium sulfate group showed good response while even at 60 minute, 13.3% of patient in the control group failed to be included as good responder. They concluded that it is evident that nebulization by isotonic magnesium sulfate solution with salbutamol provided early and better response in acute asthma as compared to conventional approach (salbutamol plus normal saline).

In **Kose et al.,** study, researchers compared the efficacy of nebulized salbutamol and magnesium sulfate in moderate bronchiolitis. They found that clinical scores of bronchiolitis were lower in the salbutamol plus magnesium sulfate group when compared with the magnesium sulfate and salbutamol groups. They concluded that nebulized magnesium sulfate plus salbutamol may have additive effects in improving the short-term clinical score **(Kose et al., 2014)**.

In some randomized controlled studies of children the use of magnesium was recommended, while other studies reported negative results. These different interpretations in the literature may be related to the infusion duration and dose of MgSO4, as said by **Buendia et al., (Buendia et al., 2020** and **Aniapravan et al., 2020)**.

CONCLUSION

In infants with acute bronchiolitis, nebulized magnesium sulfate with salbutamol affect the clinical

scores and hospital stay in treated children with significant improvement over other treatments lines.

Recommendations

- We recommend the use of nebulized magnesium sulfate plus salbutamol treatment as it may have a beneficial effect in infants with bronchiolitis in emergency departments.
- It is recommended to conduct further studies in this field with a wider and bigger sample size considering the possible effects of magnesium sulfate management of acute bronchiolitis.

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استنشاق مادة سلفات الماغنسيوم مقارنة باستنشاق مادة البوديزونيد في علاج النزلة الشعبية الحادة

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النزلة الشعبية الحادة هي عدوى فيروسيه بالجهاز التنفسي يتميز بانسداد الشعيبات الهوائية الصغيرة التي تسببها الالتهابات الحادة، وتورم وتنخر الخلايا المبطنة للشعيبات الهوائية الصغيرة وكذلك زيادة إفراز المخاط. ويعتبرالفيروس التنفسي هو المسؤول عن أكثر من 50٪ من الحالات.

ويستند العلاج من التهاب الشعيبات الهوائيه الفيروسي الحاد بشكل رئيسي على الرعاية الداعمة بما في ذلك اعطاء المحاليل الوريديه واستخدام خافضات الحرارة والأوكسجين, يتم استخدام موسعات الشعب الهوائية عادة في علاج التهاب الشعيبات الهوائيه الفيروسي الحاد.

الماغنيسيوم هو العامل المساعد المهم بالنسبة للتفاعلات الأنزيمية، ويلعب دورا هاما في استثارة العضلات التي تؤثر على الكالسيوم عبر أغشية الخلايا وهذا قد يعمل على توسيع الشعب الهوائيه.

سلفات الماغنيسيوم استخدمت لأول مرة في علاج مرضى الربو، وكشفت دراسات لاحقة أنه يسبب تحسنا كبيرا في الأطفال المصابين بالربو الغير مستجيبين للعلاج ب-β2 agonist, مع الاخذ في الاعتبار وجود العديد من أوجه التشابه في الأعراض الاكلينيكيه والفيسيولوجيا المرضية بين التهاب الشعيبات الهوائيه الفيروسي الحاد وهجوم الربو الحاد، لذا يقترح أن سلفات الماغنيسيوم يمكن استخدامها كعلاج جديد لهذا المرض.

الهدف من هذه الدراسة تقييم فعالية استنشاق سلفات الماغنيسيوم بالمقارنة باستنشاق عقار البيوديزونيدفي علاج الاطفال المصابين بالالتهاب الحاد في الشعيبات الهوائيه. وقد تم ادراج ستين طفلا يعانون من الالتهاب الفيروسي الحاد بالشعيبات الهوائيه وقد تم تقسيمهم بشكل عشوائي إلى ثلاث مجموعات، مجموعة "أ" عولجت باستنشاق عقار البيوديزونيد بالاضافه الي استنشاق عقار B2 agonist, وعولجت مجموعة "ب" باستنشاق عقار سلفات الماغنسيوم بالاضافه الي عقار β2-agonist, وعولجت مجموعه "ج" باستنشاق عقار β2-agonist فقط.

وقد أوضح البحث أن الاطفال الذين يعانون من الالتهاب الفيروسي الحاد بالشعيبات الهوائيه أدي استنشاق عقار سلفات الماغنيسيوم الى تحسن في الاعراض الاكلينيكيه للمرض كما أدي الي تقليل مدة الإقامة في المستشفى بالمقارنه بمجموعتي المرضي الذين عولجوا بالعقارات الاخري.