Evaluation of Efficacy of Oral Prednisolone in the Treatment of Acute Bronchiolitis in a Tertiary Level Hospital in Rajshahi

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Abstract

Bronchiolitis is a viral infection of lower respiratory tract that occurs most commonly in young children (< 2 years). It is one of the most common cause of hospitalization of infants. It has a major public health hazard throughout the world exerting significant morbidity and mortality.

Methods: This randomized controlled trial study was conducted in the Department of pediatrics, Rajshahi Medical College Hospital. Total 120 patients with acute bronchiolitis were selected who were less than two years of age. Two groups were randomly selected by lottery method. One group was given salbutamol along with prednisolone (Experimental group) another was only salbutamol (Placebo group) to compare the efficacy and evaluate the outcome of both treatment groups.

Result: The mean age of the experimental group was 7.09±4.71 months and mean age of placebo group was 5.70±4.26 months. The majority number of patients 96(80%) came from middle class family with 30(25%) houses with crowded conditions. About 16(13.3%) patients were born in preterm condition and 18(15%) were low birth weight. Among the family members 21(17.5%) had asthma and 43(35.18%) had smoking history. After treatment notable outcome clinically observed after 3 days of treatment in experimental than placebo group (p-value <0.05). Oral prednisolone reduces 1-2 days of hospital stay (p-value <0.001) compared to placebo group. The use of prednisolone reduces the severity of disease more rapidly in association with placebo group (p-value <0.001).

Conclusions: Bronchiolitis is one of the most common disease in the young children and is the frequent reason for hospitalization. Prednisolone is useful in the reducing hospital stay and improving respiratory symptoms.

Keywords: Bronchiolitis, RMCH, Prednisolone, Placebo, Respiratory Syncytial Virus (RSV)

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Introduction

Acute Bronchiolitis is one of the common serious potentially life threatening lower respiratory tract infection in infants resulting from inflammatory obstruction of the small airways.1 Bronchiolitis hospitalization consume significant health care resources. Children with bronchiolitis co-diagnosis of pneumonia have more expensive hospitalizations.2 About 21% of under five children who attend hospitals of Bangladesh for respiratory complaints, suffer from bronchiolitis.3

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Most of the children are below 6 months of age having the modal age 3 months. In Chittagong in Bangladesh bronchiolitis counted 10% of total admissions in pediatric wards.

Acute bronchiolitis is predominantly a viral disease. Respiratory Syncytial Virus (RSV) is responsible for 50-91% of cases. Virtually all children become infected with RSV within 2 years after birth. In general, about 0.5-2% of children with RSV disease need to be hospitalized for monitoring and supportive therapy. A number of therapies have been evaluated for their use in the amelioration of symptoms during acute illness with minimal evidence of benefit. Supportive therapy with oxygen and assistance with feeding remains the mainstay of treatment. In recent years corticosteroids have been employed in the treatment for infants with acute bronchiolitis with varied opinion. Evidence of better efficacy of oral prednisolone and salbutamol in our setting will encourage many physicians to apply this treatment protocol and manage their patients better.

**Materials and Methods**

It was a randomized controlled trial study from January 2017 to December 2018 (Two years) conducted in the department of Pediatrics, Rajshahi Medical College Hospital (RMCH), to evaluation of efficacy of oral prednisolone in the treatment of acute bronchiolitis. Any child under two years of age both male and female, who were hospitalized due to preceding or existing runny nose, cough breathing difficulty, chest indrawing and rhonchi on auscultation were included and patients having congenital heart disease previous repeated attacks of cough and wheezing or asthma as well as patients having clinical, laboratory or radiological evidence of Bronchopneumonia or secondary bacterial infection were excluded from this study. Purposive sampling was followed to collect sample. A total of 120 patients recruited and equally divided into two groups. We selected two groups randomly by lottery method. One group was given prednisolone along with salbutamol (experimental group) and another group was given salbutamol only (placebo group). Placebo group received salbutamol in a dose of 0.15mg/kg body weight (minimum dose 1mg) diluted with 3 ml normal saline nebulized 8 hourly and experimental group received salbutamol in same dose as placebo group with 1mg/kg of oral prednisolone for 3 days. Both groups also received oxygen therapy according to need, feeding maintained by oral nasogastric and intravenously according to severity. Treatment response was assessed daily for three days. Date of discharge was recorded for assessing length of hospital stay. Data were analyzed with Statistical package for Social Science (SPSS) version 23. Statistical software employing appropriate statistical tests. Continuous variables were analyzed using the paired or unpaired t-test as appropriate non-continuous variables (such as sex, atopy) were assessed using $\chi^2$ test. p-value less than 0.05 was considered significant. Approach from the Institutional Review Board (IRB) of RMC was obtained prior to the commencement of this study with informed consent from family members.

**Results**

Total 120 patients were selected. Their parents were interviewed by specific questionnaire and patients were undergoing some clinical examination and investigations for evaluation of efficacy of oral prednisolone in the treatment of acute bronchiolitis.

Changes in respiratory rate (RR) at different times from admission to next consecutive three days after pharmacological intervention in both experimental and placebo groups (Fig.1). Initially there was not enough difference in outcome on day 1 (experimental group mean RR 64.57/min and placebo group mean RR 64.88/min) but gradually after 3 days of administration, there was significant change (P-value<0.001), where mean respiratory rate was in experimental group 42.97/min and in placebo group 49.88/min.
Table 1: Changes in Oxygen saturation

| Follow up days                  | Mean (SD) | P value |
|---------------------------------|-----------|---------|
|                                 | Experimental | Placebo |         |
| Oxygen saturation at follow up day 1 | 90.10 ±2.52 | 90.11 ±2.48 | 0.971 |
| Oxygen saturation at follow up day 2 | 97 ±1.55 | 96.80 ±1.50 | 0.520 |
| Oxygen saturation at follow up day 3 | 98.28 ±0.69 | 98.07 ±0.86 | 0.150 |

Table-1 shows oxygen saturation of patients. Oxygen (O₂) saturation on day 1 among experimental group was 90.10%. On day 3 among experimental group O₂ saturation was 98.28% and in placebo group was 98.07%. Prednisolone has gradual effect on improvement of O₂ saturation. But there was no significant difference in improvement of O₂ saturation the groups.
**Table 2:** Effect on Rhonchi.

| Follow up | Experimental (%) | Placebo (%) | $X^2$ | $P$ |
|-----------|------------------|-------------|-------|-----|
| Day 1     | 60 (100)         | 60 (100)    |       |     |
| Day 2     | 58 (96.7)        | 59 (98.3)   | 4.61  | 0.03|
| Day 3     | 48 (80.0)        | 56 (93.3)   |       |     |

*The mean difference is significant at the level of 0.05

Table-2 shows effect of prednisolone on rhonchi. On day 1 all the patients had rhonchi and with treatment gradually decreased on the following two days and on day 3 number of patients with rhonchi reduced to 48 in experimental and 56 in placebo group ($P$-value<0.05).

Regarding chest indrawing patients with oral prednisolone showed statistically significant association between experimental and placebo group ($P$-value=0.001) showed in (table-3). Among the total 120 patients with chest indrawing 100% patients on day 1 had chest indrawing which gradually decreases on the following two days and on day 3 showed 9 patients out of 60 patients in experimental group had chest indrawing and 27 patients in placebo group out of 60 patients.

Effect of prednisolone on hospital stay shown in table-4. Mean hospital stay in experimental group was 3.38±0.66 days and in placebo group was 4.74±1.30 days that showed the significant effect on hospital stay ($P$-value<0.001), which reduces 1-2 days of hospital stay compared to non-prednisolone placebo group. The association between experimental and placebo group showed statistically significant ($P$-value<0.001) in reducing severity of the diseases.

**Table 3:** Effect on Chest indrawing.

| Follow up | Experimental (%) | Placebo (%) | $X^2$ | $P$ |
|-----------|------------------|-------------|-------|-----|
| Day 1     | 60 (100)         | 60 (100)    |       |     |
| Day 2     | 30 (50.0)        | 52 (86.7)   | 12.85 | 0.001|
| Day 3     | 9 (15.0)         | 27 (55.0)   |       |     |

*The mean difference is significant at the level of 0.05
Table 4: Effect on Hospital stay.

| Variables            | Mean (SD) | P value |
|----------------------|-----------|---------|
|                      | Experimental | Placebo | <0.001 |
| Days of hospital stay| 3.40± 0.64 | 4.73 ±1.23 |         |

n= 120
The mean difference is significant at the level of 0.05

Table-5 shows the effect of oral prednisolone on clinical severity score. Among the patients on day 1 the severity score was high with mean 7.92±0.81 in experimental and 7.95±0.72 in placebo group. After treatment with prednisolone severity scores down to 2.43±0.69 among experimental group where as in placebo group was 3.35±0.82 on day 3.

Table 5: Effect on Severity of disease.

| Variables                          | Mean (SD) | P value |
|------------------------------------|-----------|---------|
|                                    | Experimental | Placebo | <0.001 |
| Clinical severity score day1       | 7.92 ± 0.81 | 7.95 ± 0.72 | |
| Clinical severity score day2       | 3.63± 0.78 | 4.38 ± 0.95 |         |
| Clinical severity score day3       | 2.43± 0.69 | 3.35± 0.82 |         |

n= 120
The mean difference is significant at the level of 0.05

Discussion

Acute bronchiolitis is one of the common serious acute lower respiratory tract infections in infants and children resulting from inflammatory obstruction of the small airways. Bronchiolitis remains a major public health problem throughout the world exerting significant morbidity and mortality. This randomized controlled trial study was carried out at inpatient department of pediatrics, RMCH, during January 2017 to December 2018 following convenient nonprobability type of sampling technique. For the research total 120 and each group contained 60 patients of bronchiolitis were selected. Their parents were interviewed by specific questionnaire and patients were undergoing some clinical examination and investigations for evaluation of efficacy of oral prednisolone in the treatment of Acute Bronchiolitis.

Respiratory rate was measured during admission and consecutive 3 days after pharmacological
intervention in both experimental and placebo groups. Initially there was no significant differences but gradually within 3 days of administration, there was significant changes observed (P-value<0.001), where mean respiratory rate 42.97/min in experimental group and 49.98/min in placebo group (Fig.1). Similar response also observed in other study in the country. According to the findings of $O_2$ saturation by following 3 days of administration of oral prednisolone in bronchiolitis, there was gradual effect on improvement of $O_2$ saturation but in comparison didn’t have significant effect (Table-1).

During admission on day 1; 100% patients had rhonchi in the both lung fields of both groups, which gradually decreased on the following two days. There was gradual improvement and on day 3 number of patients with rhonchi reduces to 48 in experimental and 56 in placebo group (Table-2). So our study showed that oral prednisolone significantly reduces rhonchi in patients with bronchiolitis (P-value<0.05). Similar effect also seen in other studies in home and abroad. Steroid reduces edema as well as respiratory obstruction by decreasing swelling in the lower air passages and thus reduces the rhonchi.

Regarding chest indrawing (Table-3) all the patients had chest indrawing before starting prednisolone which was gradually decreased following 2 days and on day 3 number of patients with chest indrawing reduced to 9 in experimental and 27 in placebo group. This association showed statistically significant (P-value=0.001). Previous studies in the country found similar effect. Effect of oral prednisolone on hospital stay was evaluated in comparison to placebo group (Table-4). That showed significant effect on duration of hospital stay (P-value<0.001) which was 1-2 days less than placebo group. Similar result also seen in other studies.

On clinical severity score oral prednisolone effect was evaluated in comparison to placebo group (Table-5). Among the patients during admission the severity score was high with mean 7.92±0.81 in experimental and 7.95±0.72 in placebo group. Clinical severity score was reduced to 2.43±0.69 in experimental than placebo group (4.28±0.95) which is statistically significant (P-value<0.001). Steroids decreased symptoms score faster when compared with placebo.

**Conclusion**

This study addressed the efficacy of oral prednisolone in the treatment of acute bronchiolitis. By comparing with other studies, we can conclude that prednisolone is useful to wheeze or rhonchi, clinical severity as well as to reduce hospital stay when used in combination with conventional therapy.

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