

**CLINICAL EFFICACY OF NEBULIZED BUDESONIDE IN ACUTE EXACERBATION OF COPD**Nemagouda S<sup>1</sup>**HOW TO CITE THIS ARTICLE:**

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**ABSTRACT: INTRODUCTION:** Systemic corticosteroids are routinely used for the treatment of acute exacerbation of COPD (AECOPD). Preliminary studies have demonstrated that nebulised budesonide to be as efficacious as parental steroids in AECOPD. **OBJECTIVES:** To evaluate the clinical efficacy of nebulised budesonide with in AECOPD in comparison with parental steroids. **MATERIALS AND METHODS:** Patient's with AECOPD were included in the study and divided into two groups randomly. Control group who were given parental steroids and Study group received budesonide by nebulisation (2 mg every 12 hrly) for 5 days. These patients were assessed every 12 hrly from H0 to H72, day 5 and at discharge. The outcome variables studied were FVC, FEV1, PEFr, dyspnea score, spO2 and SGRQ score. Both groups received standard treatment i.e. oxygen, salbutamol plus ipratropium by nebulisation and parental antibiotics during study period. **RESULTS:** A total of 125 patients were included in the study: 65 in study group and 60 in control group. The baseline FEV1, FVC and PEFr were comparable in both groups. The mean improvement in FEV1, FVC and PEFr after 24 hrs, 72 hrs and day 5 were non-significantly increased in both the groups. Similarly, improvements in oxygen saturation and dyspnea grade at day 5 showed no significance between the two groups. Patients in the study group showed better improvement in SGRQ score as compared to control group. Mean duration of hospitalization was less in study group as compared to control group. **CONCLUSION:** Nebulised budesonide was equally as efficacious as parental steroids in AECOPD. Nebulised budesonide group had reduced duration of hospitalization and showed better improvement in SGRQ score as compared to control group.

**KEYWORDS:** COPD, FVC, FEV1, PEFr, SGRQ.

**INTRODUCTION:** Chronic obstructive pulmonary disease (COPD) is a leading cause of morbidity and mortality worldwide and results in an economic and social burden that is both substantial and increasing. COPD is the 4<sup>th</sup> leading cause of death in the United States of America (USA) and Europe<sup>1</sup>. Currently, COPD is a more costly disease than asthma and depending on country; 50-75% of the costs are for services associated with exacerbation. Tobacco smoke is by far the most important risk factor for COPD worldwide. Other important risk factors are indoor air pollution including biomass fuel exposure, occupational exposure, socio-economic status and genetic predisposition.<sup>2</sup>

An exacerbation is defined as an event in the natural course of the disease characterized by change in the patients baseline dyspnea, cough and/or, sputum that is beyond normal day-to-day variation, is acute in onset and may warrant a change in regular medication in a patient with COPD<sup>2</sup>. Systemic corticosteroids are used to treat acute exacerbation of COPD. This common clinical practice has been endorsed by various international guidelines.<sup>3,4</sup> Compared with placebo, systemic corticosteroids accelerate the recovery of expiratory flow rates and reduce the length of hospital stays in patients with acute exacerbation of chronic obstructive pulmonary disease (AECOPD) receiving standard medical treatment with bronchodilators, antibiotics and oxygen.

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Despite proof of efficacy, some concerns remain about using systemic corticosteroids to treat all patients with AECOPD. This is mainly because the short term advantages of corticosteroids may be outweighed by the occurrence of adverse effects such as hyperglycemia, myopathy<sup>5</sup> and osteoporosis.<sup>6</sup> It has recently been reported that suppression of the adrenal response is common after short term, high dose corticosteroid treatment<sup>7</sup>. In this context, the possibility of treating patients with AECOPD with inhaled corticosteroids, having less systemic adverse effects is of particular interest. Inhaled corticosteroids have a high level of topical anti-inflammatory activity and a low level of systemic activity.<sup>8,9</sup>

Preliminary data have demonstrated that nebulised budesonide to be as efficacious as parenteral corticosteroids in the treatment of acute severe asthma.<sup>10</sup> Nebulised budesonide may also be sufficiently efficacious in the management of acute exacerbation of COPD, but only limited number of studies is available which have demonstrated that it might be an alternative agent in AECOPD, instead of the parenteral steroids. Hence the present study was undertaken to know the clinical efficacy of nebulised budesonide with parenteral/oral steroids in patients with AECOPD.

**OBJECTIVES:** The objectives of the present study were

**Primary**

1. To evaluate the efficacy of nebulised budesonide in patients with acute exacerbation of COPD in comparison with parenteral /oral steroids

**Secondary**

1. To evaluate whether nebulised budesonide reduces the duration of exacerbation.
2. To evaluate the therapeutic outcome in patients with acute exacerbation of COPD.

**METHODOLOGY:** The present study was conducted in the Department of Pulmonary Medicine, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum on adult patients diagnosed to have AECOPD during the period of January 2008 to April 2009.

**Study design:** Institutional based prospective study.

**Study period:** The present study was conducted during January 2008 to April 2009.

**Source of Data:** Adults, male and female inpatients diagnosed to have AECOPD and admitted under Pulmonary Medicine Department, KLES Dr. Prabhakar Kore Hospital and Medical Research Center, Belgaum.

**Sample size:** A total of 125 inpatients diagnosed to have AECOPD were studied.

**Sampling procedure:** The sample size of 125 patients was calculated based on 80% of average number of patients admitted with AECOPD at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum for the last consecutive three years.

**Selection criteria:**

**Inclusion Criteria:** Patients with Acute Exacerbation of COPD.

**Exclusion Criteria:** Patients with specific cause for exacerbation such as Pneumothorax & Heart failure etc. Patients with a risk of imminent respiratory failure requiring mechanical ventilator or direct admission to the ICU.

**Procedure:** The study was approved by the Ethical and Research Committee of Jawaharlal Nehru Medical College, Belgaum. Patients fulfilling the inclusion criteria were selected for the study. The

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selected patients were briefed about the nature of study and written informed consent was obtained. The consented patients were included in the study. These patients were grouped into two groups randomly consisting of 60 patients in the control group and 65 patients in the study group. This grouping was done on the basis of inpatient admission, the first patient who got admitted was entered in the control group and second patient was entered in study group likewise random allocation was done. The data like demography, history were recorded.

Group 1 (control group) received parenteral / oral steroids IV hydrocortisone 200 mg tds / 40 mg of oral prednisolone) along with standard treatment that is;

- Salbutamol (2.5 mg) + Ipratropium bromide (500 µg) nebulization every sixth hourly.
- Supplemental oxygen inhalation.
- Parenteral antibiotics.
- IV fluids.
- IV Deriphyllin 1 ampoules (Amp) tds.

Group 2 (Study group) received budesonide nebulisation (2 mg diluted in 4 ml of normal saline every sixth hourly) along with standard treatment. The patients were assessed for following parameters at different intervals. Spirometry was carried out at baseline, 24 hours, and 72 hours and on fifth day according to ATS standards. Dyspnea was assessed according to the Modified Medical Research Council (MMRC) Grade. PEFr and SPO<sub>2</sub> were assessed at baseline, 24 hours, 72 hours and on fifth day. St. George Respiratory Questionnaire (SGRQ) was assessed at baseline, 24 hours and on fifth day.

**Outcome variables:** The primary outcome variables studied for the treatment efficacy were change in post bronchodilator FEV<sub>1</sub>, FVC, FEV<sub>1</sub>/FVC, PEFr. Secondary end points included the changes in dyspnea score (MMRC grade, SPO<sub>2</sub> and SGRQ score).

An adverse event is defined as any event reported by the patients from study entry to day 10 or discharge. Serious adverse events included life threatening events and events resulting in prolongation of hospitalization. Study discontinuation due to adverse events, including COPD deterioration or relapse was also monitored.

Deterioration of AECOPD while patients under study were defined as the need for treatment intensification according to the treating doctor, the development of confusion, lethargy, acute respiratory acidosis or need for mechanical ventilatory assistance.

Safety of study medication was assessed by monitoring occurrence of any adverse events during the acute and the follow up phase of the study. Complete blood cell count including eosinophils will be obtained at admission.

**Statistical Analysis:** For the various parameters mean and standard deviation (S.D.) were calculated. From baseline to three different time points comparison was made using student's paired 't' test. The comparison of the parameters in the study group and the control was done using student's unpaired 't' test. A 'p' value of less than 0.05 was considered as statistically significant.

**RESULTS:** A total of 125 patients were included in this study in 1:1 ratio. Thus 65 patients were included in study group and 60 patients were included in control group. The mean age of the patients

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in study group was  $64.20 \pm 9.11$  years while in control group it was  $62.40 \pm 11.31$  years. The duration of disease in the control group was  $6.60 \pm 4.80$  years while it was  $6.90 \pm 3.30$  in the study group. Pack years in the study group was  $8.60 \pm 4.50$  years while it was  $10.40 \pm 4.80$  in the control group ( $p < 0.001$ ). Baseline demographic characteristics and blood chemistry reports showed no statistically difference between two groups. In control group, 75% of the patients were males and 25% were females with a male to female ratio of 3:1. In study group 74% were males and 26% were females with male to female ratio of 3:1. In this study, majority of the patients belonged to age group of 51 to 60 years and 61 to 70 years. In control group 31.6% patients belonged to the age group of 51 to 60 years and another 31.6% in the age group of 61 to 70 years, whereas in study group, 36.9% patients belonged to age group of 51 to 60 years and another 33.8% patients belonged to 61 to 70 years age group. Twenty percent of the patients were more than 70 years in control group while in study group 24.6% of patients were more than 70 years. Only 13 patients were less than 50 years.

Baseline FEV<sub>1</sub> was  $0.45 \pm 0.11$  L/Sec in the study group and it was  $0.51 \pm 0.14$  L/Sec in the control group. The mean improvement in FEV<sub>1</sub> after 24 hours, 72 hours and at 5<sup>th</sup> day was  $0.53 \pm 0.15$  L/Sec,  $0.64 \pm 0.18$  L/Sec and  $0.82 \pm 0.19$  L/Sec in study group, while it was  $0.55 \pm 0.15$  L/Sec,  $0.69 \pm 0.15$  L/Sec and  $0.80 \pm 0.16$  L/Sec in control group respectively. It was observed that there was no statistical significance observed in FEV<sub>1</sub> improvement between the two groups at different intervals of the study period.

Baseline FVC observed in the study and the control group was  $0.88 \pm 0.19$  L/Sec and  $0.99 \pm 0.30$  L/Sec respectively. Improvement in FVC observed after 24 hours, 72 hours and at 5<sup>th</sup> day in the study group was  $0.99 \pm 0.18$  L/Sec,  $1.13 \pm 0.22$  L/Sec and  $1.36 \pm 0.26$  L/Sec while the improvement in FVC in the control group was  $1.06 \pm 0.31$ ,  $1.24 \pm 0.33$  and  $1.45 \pm 0.37$  L/Sec respectively. Thus it was observed that there was no significant difference observed between two groups.

Baseline PEF<sub>R</sub> in both study and control group were  $141 \pm 69.46$  L/M and  $139 \pm 91.15$  L/M respectively. When compared at different intervals, there was no statistically significant difference in PEF<sub>R</sub> values between the study group and the control group.

Baseline oxygen saturation in both control and study group were  $97\% \pm 1.65\%$  and  $97\% \pm 1.67\%$  respectively. However, when compared at different intervals that is 24 hours, 72 hours and at fifth day there was no statistical significant difference between the study group and the control group ( $p > 0.05$ ).

Overall MMRC dyspnea grade was 4 in both study and control group at baseline. There was improvement in dyspnea scale by one point in both the study group and the control group. Baseline SGRQ score observed in study and control group was  $88.76 \pm 5.32$  and  $86.43 \pm 4.75$  respectively. SGRQ score improvement after 24 hours and at 5<sup>th</sup> day in study group was  $82.55 \pm 5.35$  and  $68.95 \pm 6.75$  while it was  $82.36 \pm 4.81$  and  $70.80 \pm 7.09$  in control group respectively. Patients in study group showed better improvement in health related quality of life (HRQL) score as compared to control group at day 5 ( $p < 0.01$ ). In control group, HRQL score improved among 83.3% patients and remained same in 13.3% patients. In study group, 89.3% patients had improved HRQL score and while the score remained same among 10.7% patients. None of the patients had worsened HRQL score in study group.

A total of 58 patients (89.2%) had total hospitalization of less than 10 days in the study group. Twelve patients (20%) had more than 12 days of hospitalization in the control group, while it was

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10.8% in the study group. Thus it was observed more number of patients was discharged early in the study group as compared to control group. One patient in each group deteriorated and required intensification of treatment with including mechanical ventilation. A total of five patients (8.3%) in the control group were readmitted with relapse of AECOPD within 30 days of discharge from hospital. In the study group two patients (3.0%) were readmitted for the relapse of exacerbation during the study period.

**DISCUSSION:** A total of 125 patients were included into the study. Sixty five patients were in the study group and another sixty patients were in control group. Mean age of patients in study group was  $64. \pm 9.1$  years, while in control group it was  $62.4 \pm 11.31$  years. The duration of disease in both study and control group were  $6.9 \pm 3.3$  &  $6.6 \pm 4.8$  years respectively.

In the study by Morice et al<sup>11</sup> the mean baseline FEV<sub>1</sub> was similar in both groups (1.8 L/sec and 1.9 L/sec for prednisolone and budesonide, respectively). There was no significant difference in response to treatments. In the present study baseline FEV<sub>1</sub> was  $0.45 \pm 0.11$  L/Sec in study group and  $0.51 \pm 0.14$  L/Sec in control group. In the study group mean improvement in FEV<sub>1</sub> after 24 hours, 72 hours and at 5<sup>th</sup> day were  $0.53 \pm 0.15$  L/Sec,  $0.64 \pm 0.18$  L/Sec and  $0.82 \pm 0.19$  L/Sec in respectively while in the control group the mean improvement in FEV<sub>1</sub> was  $0.55 \pm 0.15$  L/Sec,  $0.69 \pm 0.15$  L/Sec and  $0.80 \pm 0.16$  L/Sec respectively. It was observed that there was no statistical significance observed in FEV<sub>1</sub> improvement between the two groups. Similar results were observed by Matais et al,<sup>12</sup> Gunen et al<sup>13</sup> and Wei et al.<sup>14</sup>

In study by Gunen et al<sup>13</sup> when comparison was made between groups treated with placebo, systemic steroids and nebulised budesonide, the baseline FVC was  $64.5 \pm 21.5$  L/Sec,  $57.5 \pm 17.5$  L/Sec and  $64.3 \pm 20.4$  L/Sec in group 1, group 2 and group 3 respectively. Improvement observed in FVC at 24 hour, 72 hours, 7 days and at 10<sup>th</sup> day was significantly higher in group 2 and group 3 when compared to group 1. There was no statistical significance as comparison was made between group 2 and group 3. In the present study, the baseline FVC observed in study and control group was  $0.88 \pm 0.19$  L/Sec and  $0.99 \pm 0.30$  L/Sec respectively. FVC improvement observed after 24 hours, 72 hours and at 5<sup>th</sup> day in study group was  $0.99 \pm 0.18$  L/Sec,  $1.13 \pm 0.22$  L/Sec and  $1.36 \pm 0.26$  L/Sec respectively. FVC improvement in control group was  $1.06 \pm 0.31$ ,  $1.24 \pm 0.33$  &  $1.45 \pm 0.37$  L/Sec respectively. The results of the present was similar those observed by Gunen et al<sup>13</sup> and Morris et al.<sup>11</sup>

In a study by Mirici et al<sup>15</sup> the improvement in PEFr at different intervals in both parenteral steroid and nebulised budesonide group were similar and it was observed that there was no statistical difference between two groups. In the present study baseline PEFr in both study and control group were  $141 \pm 69.46$  L/M and  $139 \pm 91.15$  L/M respectively. Similarly no statistical difference was observed among the two groups.

Mirici et al<sup>15</sup> observed in their study that oxygen saturation at baseline, at 30 minute, 6hours, 24 hours 48 hours, and at 10<sup>th</sup> day were 75.3%, 85.7%, 87.1%, 88.0%, 90.4% and 93.0% in parenteral steroid group while it was 79.70%, 87.7%, 87.0%, 88.5%, 89.2% and 92.6% in nebulised budesonide group respectively. No statistical difference was observed when comparison was made between two groups. In the present study, at base line, 24 hours, 72 hours and at 5<sup>th</sup> day, oxygen saturation was 97%, 97%, 97% and 98% in control group respectively, while it was 97%, 97%, 98% and 98% in study group respectively. Thus no statistical difference was found between the two groups. The present results were similar as those observed by Mirici et al<sup>15</sup> and Gunen et al.<sup>13</sup>

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In the present study, the MMRC grades of dyspnea at baseline, 24 hours, 72 hours and at 5<sup>th</sup> day were 4, 4, 3, and 3 in study group; while it was 4, 4, 4 and 3 in control group respectively. Compared to control group there were early improvement in severity of dyspnea in study group. But statistically this was negligible. Similar improvement in the dyspnea index has been observed by Morrice et al<sup>11</sup> and Wei et al<sup>14</sup>. Maltais et al<sup>12</sup> observed reduction in Borg Dyspnoea Scale between the nebulised budesonide group and the control group.

In the present study, the baseline SGRQ score observed in study and control group were 88.76±5.32 and 86.43±4.75 respectively. SGRQ score improvement after 24 hours and at 5<sup>th</sup> day in study group was 82.55±5.35 and 68.95 ± 6.75 while it was 82.36±4.81 and 70.80±7.09 in control group. Patients in study group showed better improvement in HQRL score as compared to control group. Mirici et al<sup>15</sup> also observed similar improvement in SGRQ score after nebulized budesonide in AECOPD patients.

In the study by Gunen et al<sup>13</sup> proportions of the patients with early (relatively) and delayed discharges did not yield any statistically significant results, between the control and study groups. In the present study, mean duration of hospitalization was it was 7±2.9 day in study group while in control group 7.25±2.8 days. More number of patients discharged early in study group as compared to control group. The overall reduction in duration of hospitalization was similar as those observed by Maltais et al<sup>12</sup> and Guozhong et al.<sup>16</sup>

In the present study, deterioration of AECOPD while patients under study was defined as the need for treatment intensification according to the treating doctor, the development of confusion, lethargy acute respiratory acidosis or necessity for mechanical ventilator assistance. One patient each in the study and control group deteriorated and they required mechanical ventilation.

Maltais et al<sup>12</sup> and Wei et al<sup>14</sup> observed that budesonide group had less systemic side effects than the groups treated with systemic steroids. In the present study the side effect profile of nebulised budesonide was excellent. No patient had any side effect due to nebulised budesonide including oral candidiasis. Thus there was no discontinuation of the patients in the study group due to side effects. Marcus et al<sup>17</sup> also observed that inhaled budesonide was well tolerated in AECOPD.

Gunen et al<sup>13</sup> showed exacerbation rates within one month of discharge were 14, eight and nine in placebo, parenteral and nebulised budesonide groups respectively. In the present study it was observed that two patients in study group and 5 patients in control group had relapse of AECOPD. Marcus et al<sup>17</sup> showed there was 70% reduction in relapse of AECOPD over a period of one year.

**CONCLUSIONS:** In the present study, it was observed that nebulised budesonide (2 mg every sixth hourly) was equally as efficacious as parenteral/oral corticosteroids study (Intra venous (IV) hydrocortisone 200 mg tds, or qid /40 mg of oral prednisolone) in AECOPD. The nebulised budesonide reduced the duration of hospitalization and showed better improvement in HRQL as compared to parenteral/oral steroids. Overall the therapeutic out come with nebulised budesonide in patients with AECOPD was good.

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Demographic Characteristics	Control Group (n=60)	Study Group (n=65)	p value
	Mean $\pm$ SD	Mean $\pm$ SD	Mean
Age (Years)	62.40 $\pm$ 11.31	64.20 $\pm$ 9.11	0.315
Duration (Years)	6.60 $\pm$ 4.80	6.90 $\pm$ 3.30	0.765
Pack years	10.40 $\pm$ 4.80	8.60 $\pm$ 4.50	0.019
Hb% (gm%)	11.50 $\pm$ 1.55	12.03 $\pm$ 1.24	0.091
TLC (/cmm)	13624.00 $\pm$ 1189.00	10589.00 $\pm$ 5513.00	0.062
B Urea (mg/dL)	47.00 $\pm$ 19.40	45.00 $\pm$ 19.15	0.700
Sr. Creatinine (mg/dL)	0.89 $\pm$ 0.31	0.83 $\pm$ 0.41	0.319

**Table 1: Demographic characteristics of the patients**

Variables		Control group (n=60) Mean $\pm$ S.D.	Study group (n=65) Mean $\pm$ S.D.
FEV <sub>1</sub> (L/sec)	Baseline	0.51 $\pm$ 0.14	0.45 $\pm$ 0.11
	24 hours	0.55 $\pm$ 0.15	0.53 $\pm$ 0.15
	72 hours	0.69 $\pm$ 0.15	0.64 $\pm$ 0.17
	5 <sup>th</sup> day	0.80 $\pm$ 0.16	0.82 $\pm$ 0.19
FVC (L/sec)	Baseline	0.99 $\pm$ 0.33	0.88 $\pm$ 0.14
	24 hours	1.06 $\pm$ 0.31	0.99 $\pm$ 0.18
	72 hours	1.24 $\pm$ 0.33	1.13 $\pm$ 0.22
	5 <sup>th</sup> day	1.45 $\pm$ 0.37	1.36 $\pm$ 0.26
FEV <sub>1</sub> /FVC%	Baseline	51.79 $\pm$ 12.38	50.66 $\pm$ 7.66
	24 hours	52.46 $\pm$ 12.96	53.05 $\pm$ 7.40
	72 hours	56.29 $\pm$ 11.33	55.76 $\pm$ 9.97
	5 <sup>th</sup> day	61.25 $\pm$ 10.27	59.21 $\pm$ 9.56
PEFR (L/min)	Baseline	139.00 $\pm$ 91.15	141.00 $\pm$ 69.46
	24 hours	166.00 $\pm$ 98.99	159.00 $\pm$ 73.24
	72 hours	201.00 $\pm$ 93.44	187.00 $\pm$ 79.90
	5 <sup>th</sup> day	254.00 $\pm$ 87.72	226.00 $\pm$ 80.84
SPO <sub>2</sub> (%)	Baseline	97.00 $\pm$ 1.76	97.00 $\pm$ 1.67
	24 hours	97.00 $\pm$ 1.52	97.00 $\pm$ 1.47
	72 hours	97.00 $\pm$ 1.48	98.00 $\pm$ 1.03
	5 <sup>th</sup> day	98.00 $\pm$ 1.05	98.00 $\pm$ 1.14
MMRC Grade	Baseline	4.00 $\pm$ 1.00	4.00 $\pm$ 1.00
	24 hours	4.00 $\pm$ 1.00	4.00 $\pm$ 1.00
	72 hours	4.00 $\pm$ 1.00	3.00 $\pm$ 1.00
	5 <sup>th</sup> day	3.00 $\pm$ 1.00	3.00 $\pm$ 1.00
SGRQ Score	Baseline	86.43 $\pm$ 4.75	88.76 $\pm$ 5.35
	24 hours	82.36 $\pm$ 4.81	82.55 $\pm$ 5.35
	5 <sup>th</sup> day	70.80 $\pm$ 7.09	68.95 $\pm$ 6.75

**Table 2: Characteristics of the patients during hospitalization**



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Interval	Control group		Study group		p value
	% Predicted Mean $\pm$ S.D.	Actual Mean $\pm$ S.D.	% Predicted Mean $\pm$ S.D.	Actual Mean $\pm$ S.D.	
Baseline	27.48 $\pm$ 10.51	0.51 $\pm$ 0.14	50.57 $\pm$ 7.98	0.45 $\pm$ 0.11	0.253
24 Hours	29.86 $\pm$ 11.26	0.55 $\pm$ 0.15	30.22 $\pm$ 9.88	0.53 $\pm$ 0.15	0.942
72 Hours	37.24 $\pm$ 12.26	0.69 $\pm$ 0.15	36.63 $\pm$ 11.82	0.64 $\pm$ 0.17	0.749
5 <sup>th</sup> Day	47.19 $\pm$ 13.92	0.80 $\pm$ 0.16	46.63 $\pm$ 14.40	0.82 $\pm$ 0.19	0.798

**Table 3: Comparison of forced expiratory volume in one second (FEV<sub>1</sub>) at different intervals**

Interval	Control group		Study group		p value
	% Predicted Mean $\pm$ S.D.	Actual Mean $\pm$ S.D.	% Predicted Mean $\pm$ S.D.	Actual Mean $\pm$ S.D.	
Baseline	40.00 $\pm$ 13.82	0.99 $\pm$ 0.33	37.79 $\pm$ 8.56	0.88 $\pm$ 0.14	0.150
24 Hours	42.94 $\pm$ 14.43	1.06 $\pm$ 0.31	42.67 $\pm$ 10.37	0.99 $\pm$ 0.18	0.650
72 Hours	50.35 $\pm$ 16.17	1.24 $\pm$ 0.33	48.35 $\pm$ 12.08	1.13 $\pm$ 0.22	0.415
5 <sup>th</sup> Day	58.68 $\pm$ 18.89	1.45 $\pm$ 0.37	58.09 $\pm$ 15.16	1.36 $\pm$ 0.26	0.803

**Table 4: Comparison of forced vital capacity (FVC) at different intervals**

Intervals	Control Group (n= 60)	Study Group (n=65)	p value
	Mean $\pm$ S.D.	Mean $\pm$ S.D.	
Baseline	51.79 $\pm$ 12.38	50.66 $\pm$ 7.66	0.277
24 Hours	52.46 $\pm$ 12.96	53.05 $\pm$ 7.40	0.882
72 Hours	56.29 $\pm$ 11.33	55.76 $\pm$ 9.97	0.439
5 <sup>th</sup> Day	61.25 $\pm$ 10.27	59.21 $\pm$ 9.56	0.093

**Table 5: Comparison of ratio between FEV<sub>1</sub>/FVC at different intervals**

Interval	Control group		Study group		p value
	% Predicted Mean $\pm$ S.D.	Actual Mean $\pm$ S.D.	% Predicted Mean $\pm$ S.D.	Actual Mean $\pm$ S.D.	
Baseline	35.10 $\pm$ 24.16	139.00 $\pm$ 91.15	36.29 $\pm$ 17.60	141.00 $\pm$ 69.46	0.828
24 Hours	41.42 $\pm$ 26.58	166.00 $\pm$ 8.99	41.34 $\pm$ 19.65	159.00 $\pm$ 73.24	0.826
72 Hours	50.42 $\pm$ 25.71	201.00 $\pm$ 93.44	48.41 $\pm$ 21.26	189.00 $\pm$ 79.90	0.654
5 <sup>th</sup> Day	63.54 $\pm$ 25.00	254.00 $\pm$ 87.72	58.16 $\pm$ 22.85	226.00 $\pm$ 80.84	0.289

**Table 6: Comparison of peak expiratory flow rate (PEFR) at different intervals**

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Intervals	Control Group (n= 60)	Study Group (n=65)	p value
	Mean $\pm$ S.D.	Mean $\pm$ S.D.	
Baseline	97 $\pm$ 1.76%	97 $\pm$ 1.67%	0.983
24 Hours	97 $\pm$ 1.52%	97 $\pm$ 1.47%	0.213
72 Hours	97 $\pm$ 1.48%	98 $\pm$ 1.03%	0.342
5 <sup>th</sup> Day	98 $\pm$ 1.05%	98 $\pm$ 1.14%	0.092

**Table 7: Comparison of oxygen saturation (SPO<sub>2</sub>) at different intervals**

Intervals	Control Group (n=60)	Study Group (n = 65)
	Mean $\pm$ SD	Mean $\pm$ SD
Baseline	4 $\pm$ 0	4 $\pm$ 0
24 Hours	4 $\pm$ 0	4 $\pm$ 0
72 Hours	4 $\pm$ 0	3 $\pm$ 0
5 <sup>th</sup> Day	3 $\pm$ 0	3 $\pm$ 0

**Table 8: Comparison of MMRC grading at different intervals**

Intervals	Control Group (n = 60)		Study Group (n = 65)		p value
	Mean $\pm$ S.D.		Mean $\pm$ S.D.		
Baseline	86.43 $\pm$ 4.75		88.76 $\pm$ 5.32		0.377
24 hours	82.36 $\pm$ 4.81		82.55 $\pm$ 5.35		0.164
5 <sup>th</sup> day	70.80 $\pm$ 7.09		68.95 $\pm$ 6.75		0.013
<b>Improvement in SGRQ score (Number of patients and percentage)</b>					
Improved	50	83.34%	58	89.30%	
Same	08	13.33%	07	10.70%	
Worsen	02	3.33%	-	-	

**Table 9: St. George Respiratory Questionnaire (SGRQ) score**

Duration	Control Group (n=60)		Study Group (n=65)	
	No.	Percentage	No.	Percentage
5 days	13	21.7%	25	38.4%
6 to 10 days	35	58.3%	33	50.8%
> 10 days	12	20.0%	07	10.8%
<b>Total</b>	<b>60</b>	<b>100%</b>	<b>65</b>	<b>100%</b>

**Table 10: Duration of hospitalization (days)**

Groups	Patients		p value
	No.	Percentage	
Control group (n=60)	1	1.7%	NS
Study group (n=65)	1	1.5%	

**Table 11: Number of patients deteriorated during the study**

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Groups	Patients		P value
	No.	Percentage	
Control group (n=60)	5	8.3%	0.220
Study group (n=65)	2	3.0%	

**Table 12: Relapse of exacerbation**

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