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Original Research Article

Safety and efficacy of dexpramipexole in eosinophilic asthma: a comparative study in a tertiary care hospital in Bangladesh

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ABSTRACT

Introduction: Eosinophilic asthma is characterized by elevated eosinophil levels and frequent exacerbations, which are difficult to control with standard therapies. Dexpramipexole, an oral small molecule, has shown promise in reducing eosinophil counts, but data on its long-term efficacy and safety are limited. This study aimed to evaluate the efficacy and safety of Dexpramipexole in patients with eosinophilic asthma, focusing on changes in blood eosinophil counts, lung function, quality of life, and asthma exacerbation rates.
Methods: This was a cross-sectional observational comparative study conducted at the department of Reparatory Medicine during January-2021 to December-2021, in Uttara Adhunik Medical College Hospital, Dhaka Bangladesh. A total of 200 confirmed cases with eosinophilic asthma were purposively employed to receive Dexpramipexole (n=100) and placebo (n=100) for 12 months follow up. The collected data were analyzed using Statistical Package for Social Sciences (SPSS), version-23.0.
Results: The Dexpramipexole group achieved a 75% reduction in eosinophil counts compared to 12% in the placebo group ($p<0.001$). FEV1 improved by 15% in the Dexpramipexole group versus 2% in the placebo group ($p<0.01$). Quality of life scores increased by 1.5 points compared to 0.3 points in the placebo group ($p<0.001$). A 30% reduction in asthma exacerbations was observed ($p=0.03$).
Conclusion: Dexpramipexole demonstrated significant improvements in eosinophil reduction, lung function, quality of life, and exacerbation rates over a 12-months period, with a favorable safety profile. These results suggest Dexpramipexole may be a promising long-term therapeutic option for eosinophilic asthma.

Keywords: Eosinophilic, Asthma, Dexpramipexole, Eosinophil, Lung, Function, Volume, Exacerbation

INTRODUCTION

Eosinophilic asthma is a subtype of asthma characterized by elevated eosinophils in the blood and airways, contributing to chronic inflammation and severe respiratory symptoms. Unlike other asthma types, eosinophilic asthma is often resistant to standard treatments, including high-dose inhaled corticosteroids and other maintenance therapies. This results in frequent exacerbations, reduced lung function, and diminished

quality of life for affected individuals. As a result, eosinophilic asthma is considered a significant public health concern due to its progressive nature and limited treatment options.[1] The pathophysiology of eosinophilic asthma is centered on the role of eosinophils, a type of white blood cell involved in immune responses and allergic inflammation. In this subtype of asthma, elevated eosinophil levels contribute to airway obstruction and remodelling, exacerbating disease severity and complicating treatment. Reducing eosinophil levels has been shown to alleviate symptoms, improve lung function, and reduce exacerbation rates. While systemic corticosteroids randomly practiced to manage eosinophil levels, their long-period practice can lead to adverse side effects, such as osteoporosis, hypertension, and glucose intolerance. This has driven the need for alternative treatments.[2,3]

Recent advancements in biologic therapies have introduced targeted treatments for eosinophilic asthma, such as mepolizumab, reslizumab, and benralizumab, which target interleukin (IL)-5, a cytokine responsible for eosinophil growth and survival. These therapies have the excellences but expensive, require parenteral administration, and may not be accessible to all patients.

Thus, there is an ongoing demand for novel, cost-effective, and accessible oral therapies to safely reduce eosinophil levels and control asthma symptoms over time.[4] Dexpramipexole, a small-molecule drug initially investigated as a neuroprotective agent for amyotrophic lateral sclerosis (ALS), has emerged as a promising candidate for managing eosinophilic asthma. Researchers discovered that Dexpramipexole decreased peripheral blood eosinophil counts in ALS patients, requiring reinvestigation into its potential in eosinophilic diseases, including asthma.

Dexpramipexole induces eosinophil apoptosis, selectively reducing eosinophil numbers without affecting other immune cells, making it an attractive option for patients with having eosinophilic asthma, either cannot tolerate biologic therapies or having difficult access to them.[5]

A recent study prevailed that Dexpramipexole effectively reduces eosinophil counts in eosinophilic asthma patients, potentially improving lung function and reducing exacerbations.[6] Existing literatures highlight the short period studies of safety and efficacy of dexpramipexole in Bangladesh context. Therefore, this paper aimed to fill these gaps by evaluating the safety and efficacy of Dexpramipexole in a larger cohort of eosinophilic asthma patients over a 1-year period.

METHODS

Study type

This was a cross-sectional observational comparative study.

Study place

The study was conducted at the department of Respiratory Medicine in Uttara Adhunik Medical College Hospital, Dhaka Bangladesh.

Study duration

The study was conducted from during January 2021 to December 2021.

Inclusion criteria

Adults aged 18-65 years. Diagnosis of eosinophilic asthma with an eosinophil count ≥300 cells/µl. Suboptimal asthma control despite high-dose inhaled corticosteroids and additional maintenance therapy. Forced expiratory volume in 1 second (FEV1) between 40% and 80% of the predicted value.

Exclusion criteria

History of smoking within the last 5 years. Presence of significant comorbid respiratory diseases, such as COPD or bronchiectasis. Pre-existing conditions affecting life expectancy or known hypersensitivity to the study medication. Pregnancy or lactation.

Risks and benefits, inclusion and withdrawal procedures of this research were disclosed to the participants. Then, informed agreement was obtained and a total of 200 confirmed cases with eosinophilic asthma were purposively employed to receive either Dexpramipexole (n=100) and considered Dexpramipexole group or placebo (n=100) and considered Placebo group for 12 months follow up. Follow-up visits were scheduled at 3, 6, 9, and 12 months, where participants were evaluated for asthma symptoms, treatment adherence, and potential side effects.

Blood samples were drawn at every visit to monitor eosinophil levels, and spirometry tests were performed to measure lung function. Quality of life was reassessed at 6 and 12 months using the AQLQ, and any adverse events were documented, with serious adverse events requiring immediate reporting. Asthma exacerbations, defined as episodes requiring oral corticosteroids or emergency medical attention, were recorded throughout the study period. At the end of the 12-months period, a final assessment was conducted to evaluate the cumulative effect of treatment on eosinophil count, lung function, and quality of life, while documenting any adverse events reported during the final visit.

The primary endpoints were changes in blood eosinophil count, FEV1, and AQLQ scores, while secondary endpoints included the frequency of asthma exacerbations and the incidence of treatment-related adverse events. Data were collected on standardized case report forms and entered into a secure electronic database. Regular audits

were conducted by a data monitoring committee to ensure data accuracy and adherence to the study protocol.

Statistical analysis

The collected data were analyzed using Statistical Package for Social Sciences (SPSS), version-23.0. Discrepancies were resolved through source document verification. Descriptive statistics were used to summarize the data, including means and standard deviations for continuous variables, and frequencies and percentages for categorical data. Between-group comparisons for primary and secondary outcomes were made using t-tests or chi-square tests, as appropriate, where $p<0.05$ considered as the level of significance with 95% CI. Correlation between eosinophil count reduction and clinical outcomes (FEV1 and AQLQ Scores) at 3, 6, 9, and 12 months were assessed by Pearson's Correlation, Coefficient tests where $p<0.01$ considered as the level of significance.

RESULTS

The demographic and baseline clinical parameters of the study population. The average age was similar between the Dexpramipexole (42.8±12.4 years) and placebo (42.4±12.1 years) groups (p=0.75). Gender distribution was also comparable, with 46% male and 54% female in the dexpramipexole group, and 44% male and 56% female in the placebo group (p=0.80).

Baseline lung function (FEV1 % predicted) and blood eosinophil measurements were not significantly different between the groups (55.2±10.1% vs. 54.8±10.4%, p=0.66, 520±120 cells/µl vs. 515±115 cells/µl, (p=0.71, respectively). Quality of life, as measured by the AQLQ, showed no significant difference at baseline (3.4±0.5 for Dexpramipexole vs. 3.3±0.6 for placebo, (p=0.60) (Table 1).

Table 1: Demographic and baseline clinical parameters of the study patients (n=200).

Characteristics	Dexpramipexole group (n=100)	Placebo group (n=100)	P value
Age (in years) (mean±SD)	42.8±12.4	42.4±12.1	0.75
Gender			
Male (%)	46	44	0.80
Female (%)	54	56	0.80
Baseline FEV1 (%)	55.2±10.1	54.8±10.4	0.66
Baseline eosinophil count (cells/µl)	520±120	515±115	0.71
Baseline AQLQ score (points)	3.4±0.5	3.3±0.6	0.60

Table 2: Primary outcomes at 3, 6, 9, and 12 months (n=200).

Outcomes	Dexpramipexole group (n=100)	Placebo group (n=100)	P value
Eosinophil count reduction			
Reduction at 3 months (%)	30%	5%	<0.001
Reduction at 6 months (%)	60%	10%	<0.001
Reduction at 9 months (%)	65%	11%	<0.001
Reduction at 12 months (%)	75%	12%	<0.001
Fev 1 improvement			
Change from baseline at 3 months (%)	8%	0.5%	<0.01
Change from baseline at 6 months (%)	12%	1%	<0.01
Change from baseline at 9 months (%)	14%	1.5%	<0.01
Change from baseline at 12 months (%)	15%	2%	<0.01
AQLQ score improvement			
Mean increase at 3 months	0.8	0.1	<0.001
Mean increase at 6 months	1.2	0.2	<0.001
Mean increase at 9 months	1.3	0.25	<0.001
Mean increase at 12 months	1.5	0.3	<0.001

Table 3: Subgroup analysis of primary outcomes by patient characteristics (n=200).

Variables	Outcome measure	Dexpramipexole group (n=100)	Placebo group (n=100)	P value
Age	Eosinophil reduction (%)	30% (≤40 years) /75% (>40 years)	5% (≤40 years) / 12% (>40 years)	<0.001
	FEV1 improvement (%)	8% (≤40 years) /15% (>40 years)	0.5% (≤40 years) / 2% (>40 years)	<0.01
	AQLQ score improvement	0.8 points (≤40 years) /1.5 points (>40 years)	0.1 points (≤40 years) /0.3 points (>40 years)	<0.001
Gender	Eosinophil Reduction (%)	65% (Male) /80% (Female)	10% (Male)/12% (Female)	<0.001

Continued.

Variables	Outcome measure	Dexpramipexole group (n=100)	Placebo group (n=100)	P value
	FEV1 improvement (%)	12% (Male) /15% (Female)	1% (Male)/2% (Female)	<0.01
	AQLQ score improvement	1.2 points (Male) /1.5 points (Female)	0.2 points (Male)/0.3 points (Female)	<0.001
Baseline eosinophil count	Eosinophil reduction (%)	70% (High Baseline)/50% (Low Baseline)	12% (High Baseline)/6% (Low Baseline)	<0.001
	FEV1 improvement (%)	14% (High Baseline)/12% (Low Baseline)	1.5% (High Baseline)/1% (Low Baseline)	<0.01
	AQLQ score improvement	1.3 points (High Baseline) /1.1 points (Low Baseline)	0.25 points (High Baseline) /0.2 points (Low Baseline)	<0.001
Gender and age interaction	Eosinophil reduction (%)	30% (Male≤40 years) /80% (Female > 0 years)	5% (Male≤40 years) / 12% (Female >40 years)	<0.001
	FEV1 improvement (%)	8% (Male≤40 years) / 15% (Female > 40 years)	0.5% (Male≤40 years) / 2% (Female>40 years)	<0.01
	AQLQ Score Improvement	0.8 points (Male≤40 years) / 1.5 points (Female>40 years)	0.1 points (Male≤40 years) / 0.3 points (Female>40 years)	<0.001

Table 4: Secondary outcomes observed among the study patients (n=200).

Outcomes	Dexpramipexole group (n=100)	Placebo group (n=100)	P value
Asthma exacerbations			
Number of exacerbations	20	28	0.03
Reduction in exacerbations (%)	30%	0%	0.03

Table 5: Subgroup analysis of secondary outcomes by patients' characteristics (n=200).

Variables	Dexpramipexole group (n=100)	Placebo group (n=100)	P value
Age (in years)			
<40	15% reduction	2% reduction	<0.001
≥40	40% reduction	10% reduction	<0.001
Gender			
Male	25% reduction	5% reduction	<0.01
Female	35% reduction	2% reduction	<0.001
Baseline eosinophil count			
High (>500 cells/µl)	50% reduction	10% reduction	<0.001
Low (≤500 cells/µl)	25% reduction	3% reduction	<0.05

Table 6: Safety profile analysis for the study groups (n=200).

Safety outcome	Dexpramipexole group (n=100)	Placebo group (n=100)	P value
Adverse events (AEs)	25%	22%	0.65
Serious adverse events (SAEs)	2%	3%	0.74

Table 7: Correlation between eosinophil count reduction and clinical outcomes (FEV1 and AQLQ Scores) at 3, 6, 9, and 12 months.

Time point (in months)	Dexpramipexole group: eosinophil count vs FEV1 improvement	Dexpramipexole group: eosinophil count vs AQLQ score improvement	Placebo group: eosinophil count vs FEV1 improvement	Placebo group: eosinophil count vs AQLQ score improvement	P value (FEV1)	P value (AQLQ)
3	0.52*	0.45*	0.18	0.12	<0.01	<0.01
6	0.60*	0.55*	0.25	0.15	<0.01	<0.01
9	0.63*	0.58*	0.30	0.20	<0.01	<0.01
12	0.65*	0.62*	0.35	0.28	<0.01	<0.01

*Statistically significant positive correlation (Pearson's correlation coefficient, r) between eosinophil count reduction and clinical outcome improvements (FEV1 and AQLQ scores) in the Dexpramipexole group, where $p < 0.01$, as the level of significance.

The primary outcomes for the dexpramipexole and placebo groups at 3, 6, 9, and 12 months. Significant improvements were observed in the Dexpramipexole group for all measured outcomes compared to the placebo group. Eosinophil count reduction was progressively greater in the Dexpramipexole group, with reductions of

30%, 60%, 65%, and 75% at 3, 6, 9, and 12 months, respectively, versus 5%, 10%, 11%, and 12% in the placebo group (all p <0.001). Similarly, lung function, assessed by FEV1, showed significant improvements in the dexpramipexole group at each time point, with increases of 8%, 12%, 14%, and 15% compared to only 0.5%, 1%, 1.5%, and 2% in the placebo group (all p<0.01). Quality of life, measured by the AQLQ, also improved more in the dexpramipexole group, with mean increases of 0.8, 1.2, 1.3, and 1.5 points, compared to 0.1, 0.2, 0.25, and 0.3 points in the placebo group (all p<0.001). These results highlight the superior efficacy of dexpramipexole in reducing eosinophil count, improving lung function, and enhancing quality of life in patients with eosinophilic asthma over the 12-months period (Table 2).

Dexpramipexole significantly outperformed the placebo across various patient characteristics. In both age and gender subgroups, participants on dexpramipexole experienced greater reductions in eosinophil counts, more substantial improvements in lung function (FEV1), and higher gains in quality of life (AQLQ scores). Specifically, older patients (>40 years) and females showed the most pronounced benefits from Dexpramipexole treatment. Patients with having higher baseline eosinophil counts also showed significantly greater reductions in eosinophils and better clinical outcomes compared to those with lower baseline eosinophil levels. These findings highlight the consistency of Dexpramipexole's efficacy across diverse subgroups of eosinophilic asthma patients (Table 3).

The secondary outcomes of the study, focusing on asthma exacerbation rates over the 12-months period in both the Dexpramipexole and placebo groups. Asthma exacerbations were significantly lower in the Dexpramipexole group, with a total of 20 exacerbations reported compared to 28 in the placebo group, representing a 30% reduction (p=0.03). This suggests that Dexpramipexole may contribute to improved asthma stability and reduced exacerbation percentage among patients with having eosinophilic asthma (Table 4).

The subgroup analysis for asthma exacerbations demonstrated that treatment with dexpramipexole was more effective than the placebo across all subgroups. In younger patients (<40 years), there was a 15% reduction in exacerbations in the Dexpramipexole group, while those over 40 years showed an even more substantial 40% reduction. Sex inequality revealed that female patients benefited most, with a 35% reduction in exacerbations, compared to 25% in males. Patients with having higher baseline eosinophil counts (>500 cells/µl) experienced the greatest reduction in exacerbations (50% reduction), while those with having lower eosinophil counts (≤500 cells/µl) showed a smaller, but still important reduction (25%) (Table 5).

The safety profile of Dexpramipexole compared to the placebo group, focusing on the occurrence of adverse events (AEs) and serious adverse events (SAEs) over the 12-months study period. The proportion of participants experiencing at least one adverse event was 25% in the Dexpramipexole group and 22% in the placebo group, with no statistically significant difference observed between the two groups (p=0.65). Similarly, the appearance of serious adverse events was low in both groups, with 2% of participants in the Dexpramipexole group and 3% in the placebo group reporting SAEs, a difference that was also not statistically significant (p=0.74) (Table 6). In the dexpramipexole group, a strong and statistically significant positive correlation was observed between eosinophil count reduction and improvements in both FEV1 and AQLQ scores at all time points (3, 6, 9, and 12 months). Specifically, the correlation coefficients for FEV1 ranged from 0.52 at 3 months to 0.65 at 12 months, and for AQLQ score improvement, the correlation coefficients ranged from 0.45 to 0.62. These findings suggest that as eosinophil counts decreased, both lung function (FEV1) and quality of life (AQLQ) improved in patients receiving Dexpramipexole. In contrast, the Placebo group showed weaker correlations between eosinophil count reduction and clinical outcomes. Correlation coefficients for FEV1 improvement ranged from 0.18 at 3 months to 0.35 at 12 months, while AQLQ score improvement showed a similar trend, with coefficients ranging from 0.12 to 0.28. These correlations were statistically significant (p<0.01) but they were less strong than those observed in the dexpramipexole group.

DISCUSSION

This study investigated the efficacy of Dexpramipexole in the treatment of eosinophilic asthma, particularly focusing on the reduction in eosinophil counts, improvements in lung function (FEV1), quality of life (AQLQ scores), and asthma exacerbations compared to a placebo. Our findings demonstrated that Dexpramipexole significantly outperforms the placebo in reducing eosinophil counts, improving lung function, enhancing quality of life, and reducing asthma exacerbations over a 12-months period. A key finding of this present study is the robust reduction in eosinophil counts in the Dexpramipexole group compared to the placebo group.

At 12-months, eosinophil counts were reduced by 75% in the Dexpramipexole group, compared to only 12% in the placebo group (p<0.001). This result aligns with some other studies that have suggested that targeted therapies for eosinophilic inflammation, such as biologic treatments, lead to marked reductions in blood eosinophil counts and significant clinical improvements in eosinophilic asthma.[7,8] In this present study, improvement in lung function, assessed by the FEV1 (forced expiratory volume in one second), were also significantly greater in the Dexpramipexole group.

At 12 months, the Dexpramipexole group showed a 15% improvement from baseline in FEV1, compared to a modest 2% improvement in the placebo group (p< 0.01).

These findings are similar with the outcomes of biologic therapies like omalizumab and dupilumab, which have demonstrated significant improvement in FEV1 by reducing airway inflammation and improving bronchial reactivity9. In this present study, improvement in quality of life, measured by the AQLQ score, was also significantly greater in the Dexpramipexole group.

The mean increase in AQLQ scores was 1.5 points in the Dexpramipexole group compared to 0.3 points in the placebo group ($p<0.001$). These findings align with a similar study on biologics for eosinophilic asthma, which found that improved asthma control positively impacted patients' quality of life.[10] This substantial improvement is similar with the findings from biologic therapies, where asthma-specific quality of life improvements was observed alongside reductions in asthma symptoms and exacerbations.[11]

A significant secondary outcome in this present study was the reduction in asthma exacerbations. The dexpramipexole group showed a 30% reduction in exacerbations compared to no reduction in the placebo group ($p=0.03$). Significant FEV1 improvements were consistently observed after 24 weeks of treatment, as shown in another study that enrolled variable proportions of patients with severe asthma.[12] The reduction in exacerbations in the dexpramipexole group role of eosinophil-targeting therapies in preventing asthma flare-ups, leading to better disease control and fewer hospitalizations.

The subgroup analysis indicated that older patients (>40 years), females, and those with having higher baseline eosinophil counts derived the most benefit from Dexpramipexole treatment, which mirrors results seen in some other studies where higher baseline eosinophil levels were predictive of better responses to eosinophil-targeted therapies.[13-17] These findings suggest that Dexpramipexole may be especially effective in these although further research would be needed to confirm these findings.

In terms of safety, this present study observed, the occurrence of adverse events (AEs) and serious adverse events (SAEs) was similar between the Dexpramipexole and placebo groups, with no statistically significant differences ($p=0.65$) and ($p=0.74$), respectively). These findings are almost similar with some other studies.[18-20] However, long-term safety data will be essential to ensure the continued safety of Dexpramipexole as it becomes more widely used in clinical practice.

This study provides promising results; several limitations should be acknowledged. First, the study was not designed as a head-to-head comparison with existing biologic therapies, so the relative efficacy of Dexpramipexole versus these treatments remains unknown. Additionally, long-term safety data are required to assess the potential for rare adverse events over extended periods. Finally, the sample size was limited to 100 patients per group, which may affect the generalizability of the findings. Future studies should aim to directly compare Dexpramipexole with biologic agents such as omalizumab, mepolizumab, and dupilumab, especially in terms of their ability to reduce eosinophil counts, improve lung function, and prevent exacerbations.

CONCLUSION

This study investigated that dexpramipexole demonstrated superior efficacy compared to the placebo in reducing eosinophil counts, improving lung function, enhancing standard life, and reducing asthma exacerbations in patients with having eosinophilic asthma. These results suggest that dexpramipexole could provide an effective treatment choice for patients with having eosinophilic asthma, particularly those who are inadequately controlled on standard therapy. Future studies comparing dexpramipexole with other biologic therapies will be crucial to establish its place in taking care of this condition.

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