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ORIGINAL RESEARCH

Evaluating Prescription Patterns, Quality of Life, Therapeutic Adherence, and Pharmaco-Economic Impact in Interstitial Lung Disease Patients: A Study from a Tertiary Care Center in North India

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ABSTRACT

Objective: The objective of this study was to monitor and evaluate prescription patterns for interstitial lung diseases (ILDs) at a tertiary care center in North India, specifically aiming to assess adherence to NICE guidelines, examine the impact of these practices on patients' quality of life and therapeutic adherence, and conduct a pharmaco-economic analysis to determine the cost-effectiveness of the treatments provided.**Methodology:** This 12-month prospective study at King George's Medical University involved 85 ILD patients. Prescription patterns were monitored with a CRF and NICE guidelines. Adherence was categorized as low, medium, or high. Quality of life was measured using the K-BILD questionnaire (0–100). Pharmacoeconomic analysis evaluated the cost and effectiveness of therapeutic regimens. The data was analyzed with SPSS version 23.0.**Results:** The study of 84 participants highlights a diverse demographic with a prevalence of hypersensitivity pneumonia and a significant association between smoking and idiopathic pulmonary fibrosis. Methylxanthines and oral corticosteroids are the most commonly prescribed medications, while nintedanib is favored in disease-modifying treatments. Significant cost variations are observed in both single-drug and fixed-dose combinations, impacting treatment affordability. The study also notes declining quality of life, low medication adherence, and a focus on supportive care with minimal use of invasive procedures.**Conclusion:** This study highlights hypersensitivity pneumonitis and a preference for methylxanthines and oral corticosteroids. It reveals significant cost variations in drug prescriptions, with some four-drug combinations proving more cost-effective despite higher costs. The findings stress the need for a balanced approach to cost and efficacy, improved medication adherence, and strategies to manage cost variability, aligning with previous research on ILD treatment.

Keywords: Interstitial Lung Disease (ILD); Quality of Life; Therapeutic Adherence; Pharmaco-Economic Analysis; North India; Respiratory Diseases; Health Quality Indicators

INTRODUCTION

Interstitial lung disease (ILD) (diffused parenchymal diseases) encompasses a diverse group of more than 200 rare pulmonary disorders characterized by inflammation and fibrosis of the lung parenchyma [1] associated with substantial morbidity and mortality. These are classified on the basis of histopathological, radiologic and clinical parameters. Idiopathic pulmonary fibrosis (IPF) is the most prevalent form, recognized for its progressive fibrosis and distinctive radiological pattern known as usual interstitial pneumonia (UIP) [2].

Many of the subsets of the disease are of unknown etiology. Regardless, they all ultimately share the same manner of development. The morphological changes seen histologically result from a sequence of inflammation within the parenchyma, which is the portion of the lung involved in gas exchange

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(the alveoli, the alveolar ducts, and the bronchioles). This compartment is the habitat to various proteins and pro-fibrotic elements. These proteins, after repeated cycles of activation, give rise to accumulation of connective tissue [3]. The trigger can be a known agent that deposited within the lung tissues. In some cases, the fibrosis arises spontaneously.

Despite advancements in understanding and treatment, managing ILD remains complex due to the variety of underlying causes, including idiopathic, environmental, occupational, and connective tissue-related factors [4].

Current treatment strategies for ILD are guided by evidence-based guidelines, such as those from the National Institute for Health and Care Excellence (NICE). However, discrepancies in prescription patterns and adherence to these guidelines can impact patient outcomes. Effective management requires not only adherence to guidelines but also a comprehensive approach that addresses therapeutic adherence, quality of life, and the economic implications of treatment.

This study aims to evaluate prescription patterns for ILD at a tertiary care center in North India, assessing adherence to NICE guidelines and its impact on patient quality of life and therapeutic adherence. Additionally, the study performs a pharmaco-economic analysis to determine the cost-effectiveness of current treatment strategies. By providing insights into these areas, the research seeks to identify potential gaps in treatment practices and inform strategies for optimizing care for ILD patients.

MATERIAL AND METHODS

This prospective observational study was carried out in the Department of Pharmacology and Therapeutics in collaboration with the Department of Respiratory Medicine at King George's Medical University (KGMU), Lucknow. The study extended over a period of 12 months and centered on a cohort of patients diagnosed with interstitial lung disease (ILD). A total of 85 participants were included in the study.

The study included patients presenting with fever, cough, and shortness of breath at the Respiratory Medicine OPD of KGMU, Lucknow, who had unexplained respiratory symptoms and HRCT findings suggestive of interstitial lung disease (ILD). Participants were required to be between 18 and 60 years of age, irrespective of sex. Exclusion criteria were individuals with incomplete medical records, those under 18 years old, pregnant or lactating women, patients with malignant conditions, immunocompromised individuals, those with psychotic disorders, individuals with suspected recent or active infections, and those unwilling or unable to provide informed consent.

The methodology of the study involved several key components. Prescription patterns were monitored using a Case Record Form (CRF) and evaluated according to NICE guidelines. Therapeutic adherence was assessed through a questionnaire that classified adherence into three levels: low (<6), medium (6 to <9), and high (9 to 10) [5]. Quality of life was measured using the King's Brief Interstitial Lung Disease (K-BILD) questionnaire, which evaluates health impairments related to ILD through 15 questions across three domains—'breathlessness and activity,' 'chest symptoms,' and 'psychological impact'—using a seven-point Likert Scale [6]. Scores range from 0 to 100, with higher values indicating better health. Pharmacoeconomic analysis of the therapeutic regimens was performed based on data collected during the initial visit and monitored through subsequent follow-up visits [7]. The assessment involved dividing patients into two groups for comparative analysis. The calculations will be conducted based on the following parameters: For cost minimization analysis, various groups of therapeutic regimens was compared to determine which has the lowest cost. This comparison was quantified as the percentage variation in cost among the different groups. In contrast, the cost-effectiveness analysis evaluates the different groups of therapeutic regimens based on their relative efficacy, focusing on identifying which regimens offer superior outcomes in terms of effectiveness.

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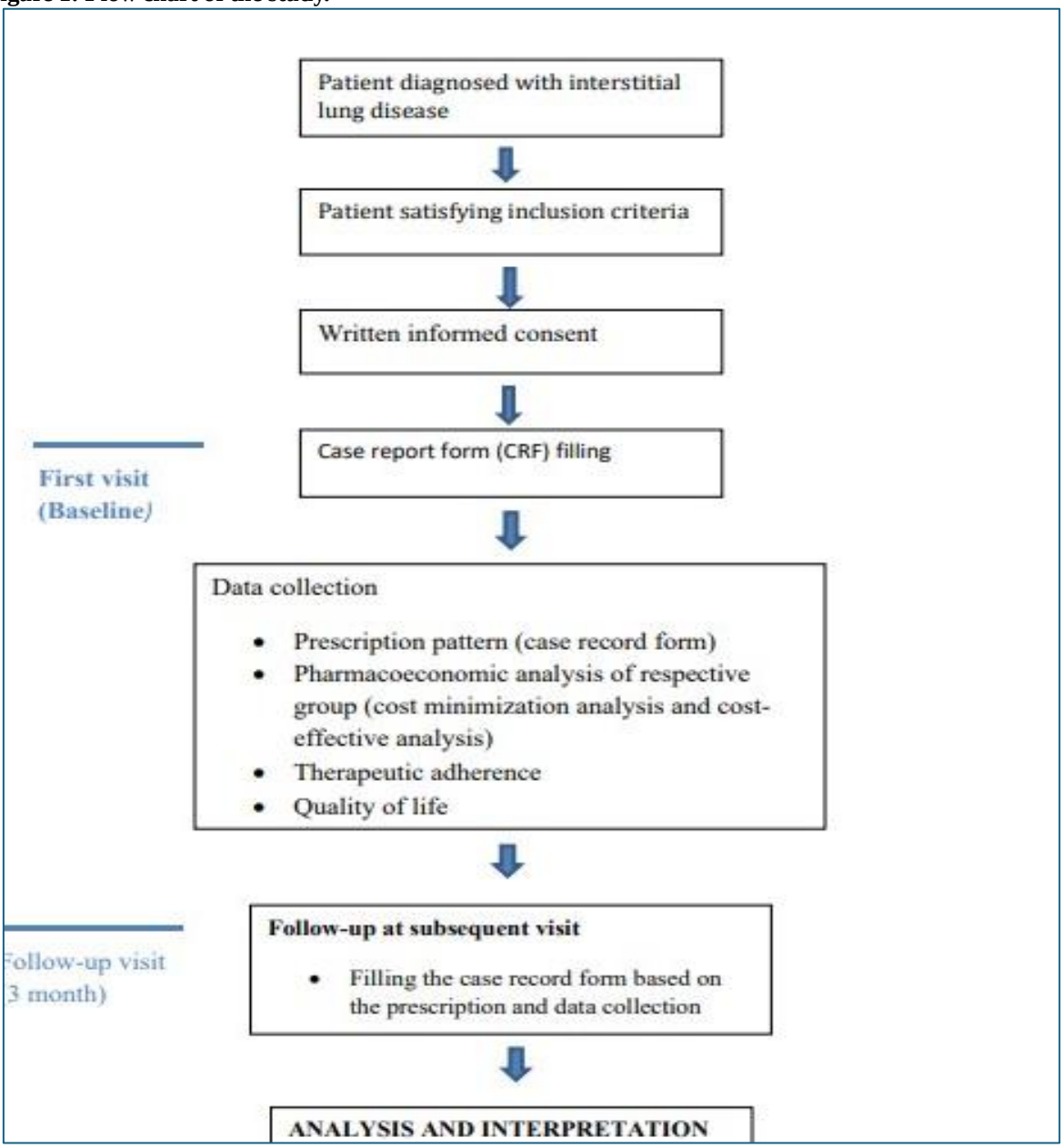
Figure 1: Flow chart of the study.



Statistical Analysis

Categorical variables are presented as counts and percentages (%), while continuous variables are expressed as means and standard deviations (SD). To compare baseline and follow-up data, paired t-tests were utilized. Qualitative variables were compared using the Chi-Square test or Fisher's Exact test, as appropriate. A p-value of <0.05 was deemed statistically significant. Data entry was performed using MS Excel, and statistical analysis was conducted with Statistical Package for the Social Sciences (SPSS) version 23.0.

RESULTS

The study, encompassing 84 participants, reveals a diverse demographic profile. Age-wise, the majority are between 31 and 50 years old, with 31.0% aged 31-40, 33.3% aged 41-50, and 27.4% aged 51-60. The gender distribution shows a predominance of males at 64.3%, while females constitute 35.7%; there are no significant age differences between genders (p-value 0.802). In terms of occupation, homemakers and individuals exposed to dust are the most common, comprising 34.5% and 38.1% of the participants, respectively. Fewer participants are office workers (9.5%), students (2.4%), or in other occupations (15.5%). Socio-economically, the largest group is from the upper-lower category (40.5%), followed by lower middle (23.8%), upper middle (14.3%), and an equal split between lower and upper categories (10.7% each). Additionally, 39.3% of the participants are smokers, while 60.7% are non-smokers.

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Table 1: Demographic and Occupational Distribution of the Study Population.

Category	Subcategory	N	%
Age Distribution	18-30 years	2	2.4%
	31-40 years	26	31.0%
	41-50 years	28	33.3%
	51-60 years	23	27.4%
	>60 years	5	6.0%
	Total	84	100.0%
Gender Distribution	Male	54	64.3%
	Female	30	35.7%
	Total	84	100.0%
Age by Gender	18-30 years (Male)	1	1.9%
	18-30 years (Female)	1	3.3%
	31-40 years (Male)	15	27.8%
	31-40 years (Female)	11	36.7%
	41-50 years (Male)	18	33.3%
	41-50 years (Female)	10	33.3%
	51-60 years (Male)	17	31.5%
	51-60 years (Female)	6	20.0%
	>60 years (Male)	3	5.6%
	>60 years (Female)	2	6.7%
	p-value	0.802 (NS)	
Occupation	Homemaker	29	34.5%
	Dust Exposer	32	38.1%
	Office Work	8	9.5%
	Student	2	2.4%
	Others	13	15.5%

The most common subtype is Hypersensitivity Pneumonitis (38.1%), followed by Connective Tissue Disease-Associated ILD (29.8%) and Idiopathic Pulmonary Fibrosis (20.2%). Sarcoidosis and other ILD subtypes each represent a smaller proportion of the study population. Smoking is significantly associated with certain ILD diagnoses, especially IPF (p=0.006), where a high percentage of smokers is observed. In contrast, sarcoidosis and other ILD diagnoses show little to no association with smoking.

The drug prescription patterns among the study participants, categorized into single drug prescriptions and fixed dose combinations [Table 2]. Among single drug prescriptions, **Methylxanthines** are most common (34.52%), followed by **Oral Corticosteroids**(30.95%), indicating their key roles in treatment. **Antibiotics** are used by 17.86%, and **Mucolytics** by 19.05%. Within Disease Modifying Pharmacological Interventions, **Nintedanib** is preferred (45.00%) over **Pirfenidone** (15.00%). For fixed dose combinations, the **Inhaled Corticosteroid + Beta Agonist** combination is the most prevalent (25.00%), with the **Inhaled Corticosteroid + Beta Agonist + Anticholinergic** combination used by 20.24%. **Antibiotic Fixed Dose Combinations** are used by 21.43%, and the **Endothelin Receptor Antagonist + Phosphodiesterase 5 Inhibitor** combination is less common (10.71%). Overall, the prescription patterns reflect a broad and targeted approach to managing respiratory health.

Table 2: Prescription Pattern of Drugs Prescribed to Study Participants.

Prescription Pattern	N	%
SINGLE DRUG PRESCRIPTION (Group I)		
Antibiotics (Ciprofloxacin, Levofloxacin, Azithromycin, Doxycycline)	15	17.86%
Methylxanthine	29	34.52%
Oral Corticosteroid	26	30.95%
Mucolytic	16	19.05%
Disease Modifying Pharmacological Intervention	20	23.81%
- Mycophenolate mofetil	4	20.00%
- Azathioprine	2	10.00%
- Cyclophosphamide	2	10.00%
- Nintedanib	9	45.00%
- Pirfenidone	3	15.00%
FIXED DOSE COMBINATIONS (Group II)		

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Inhaled corticosteroid + Beta Agonist	21	25.00%
Inhaled corticosteroid + Beta Agonist + Anticholinergic	17	20.24%
Endothelin receptor antagonist + Phosphodiesterase 5 Inhibitor	9	10.71%
Antibiotic (FDC)	18	21.43%

The study highlights a focus on supportive and rehabilitative care for respiratory conditions. Half of the participants received rehabilitation, and 80.95% received best supportive care. Only 2.38% were advised on lung transplant options, while all were recommended periodic follow-up. Ventilation was not utilized. The approach emphasizes ongoing care with minimal use of invasive procedures.

The data reveals a clear trend of deterioration across all domains- Breathlessness and Activity, Chest symptoms, and Psychological impact, assessed by the K-BILD questionnaire. Patients experienced significant worsening in breathlessness and activity, chest symptoms, and psychological impact from baseline to follow-up [Table 3]. The statistical significance of these changes underscores the seriousness of the decline in quality of life among the study population.

Table 3: Quality of Life Assessment Using King's Brief ILD Questionnaire (K-BILD) Across Different Domains at Baseline and Follow-Up.

Domain	N	Baseline Mean	Baseline SD	Follow-Up Mean	Follow-Up SD	Mean Difference	% Mean Change	p-value
Breathlessness and Activity	84	12.18	1.22	23.06	1.97	10.88	89.34	<0.001
Chest	84	10.06	1.47	22.12	1.37	12.06	119.88	<0.001
Psychological	84	8.44	1.19	19.93	1.64	11.49	136.11	<0.001

The majority of the study population exhibits low to medium adherence levels (92.9%). The predominance of low adherence underscores a critical area for intervention, as improving adherence could significantly enhance therapeutic effectiveness and patient outcomes.

The cost minimization analysis highlights significant cost variations within both single drug prescriptions and fixed dose combinations [Table 4]. For single drug prescriptions, substantial price discrepancies are evident**.** Methylxanthine exhibits the highest percentage cost variation at 150.20%, indicating that its cost per unit can more than double depending on the source. Similarly, Azathioprineand Doxycycline show high variations (148.45% and 109.76%, respectively), reflecting considerable differences in pricing across different suppliers. In contrast, Cyclophosphamide and Oral Corticosteroid demonstrate relatively lower cost variation, suggesting more stable pricing in these categories. Among fixed dose combinations, the cost variation is also notable. For instance, Fluticasone Propionate + Formoterol (MDI) has the highest percentage variation at 158.4%, revealing that its cost can vary significantly. Amoxicillin + Clavulanic Acid in the antibiotic fixed dose combinations shows an extreme cost variation of 210.2%, indicating that prices can vary over threefold between different suppliers. Inhaled corticosteroid combinations like Fluticasone Propionate + Salmeteroland Fluticasone furoate + Vilanterolalso show significant cost variations (103.5% and 43.9%, respectively), which could impact treatment affordability. Overall, these variations highlight the need for careful consideration of cost differences when selecting therapies, as substantial discrepancies can affect the overall cost burden of treatment. Strategies to address and minimize these cost variations could improve access to medications and reduce healthcare expenses.

Table 4: Cost Minimization Analysis of Single Prescribed Drugs (Group I) and Fixed Dose Combinations (Group II).

Category	Max Cost (Rs.)	Max Cost per Unit (Rs.)	Min Cost (Rs.)	Min Cost per Unit (Rs.)	% Cost Variation
Single Drug Prescription (Group I)					
Antibiotic					
Ciprofloxacin	42/10	4.2	19.10/10	1.91	119.89
Levofloxacin	98.56/10	9.85	53/10	5.3	85.96
Azithromycin	112.12/10	11.21	67.12/10	6.71	67.0
Doxycycline	79.50/10	7.95	37.90/10	3.79	109.76
Methylxanthine	170/10	11.7	67.94/10	6.79	150.20
Oral Corticosteroid	52.50/10	5.25	35/10	3.5	50.0

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Mucolytic	312.82/10	31.28	278.70/10	27.87	12.24
Disease Modifying Pharmacological Intervention					
Mycophenolate mofetil	980/10	98.0	586/10	58.6	67.23
Azathioprine	125/10	12.5	50.31/10	5.03	148.45
Cyclophosphamide	47.10/10	4.71	35/10	3.5	34.57
Nintedanib	935/10	93.5	735/10	73.5	27.21
Pirfenidone	347/15	23.13	200/15	13.33	73.5
Fixed Dose Combinations (Group II)					
Inhaled Corticosteroid + Beta Agonist					
Budesonide + Formoterol	235.5/30	7.85	198/30	6.6	18.9
Fluticasone Propionate + Salmeterol	342/30	11.4	168.25/30	5.60	103.5
Fluticasone Propionate + Formoterol (MDI)	770/120	6.41	298/120	2.48	158.4
Inhaled Corticosteroid + Beta Agonist + Anticholinergic					
Budesonide + Glycopyrrolate + Formoterol	381/30	12.7	290/30	9.60	32.3
Fluticasone furoate + Vilanterol	2822/60	47.03	1960/60	32.66	43.9
Endothelin Receptor Antagonist + Phosphodiesterase Inhibitor					
Ambrisentan + Tadalafil	2093/10	209.30	1592/10	159.2	31.5
Antibiotic (FDC)					
Amoxicillin + Clavulanic Acid	461.19/10	46.12	147.87/10	14.87	210.2
Azithromycin + Cefixime	300/10	30.0	152/10	15.20	97.4
Cefpodoxime + Clavulanic Acid	329/10	32.90	280/10	28.0	17.5

The table 5 summarizes the costs and efficacy of various drug combinations prescribed for ILD patients. The **4-drug combinations** generally show higher average costs compared to the **3-drug combinations**, with costs ranging from Rs. 2768 to Rs. 5320 per month. Despite their higher costs, the ACER values vary, indicating differences in cost-effectiveness. For instance, the combination of **Steroid + Beta Agonist + Methylxanthine + Anticholinergic** has a lower ACER (3690) compared to **Steroid + Beta Agonist + Ambrisentan + Tadalafil** (6018), suggesting a better cost-effectiveness ratio for the former. Among the **3-drug combinations**, **Steroid + Beta Agonist + Antibiotic** is the most cost-effective (3964), while **Antibiotic + Steroid + Methylxanthine** has a higher ACER (5915). The variations in ACER values reflect differences in the incremental benefits of FVC improvements relative to the costs of the drug combinations [Table 5]. Overall, the cost-effectiveness of these drug combinations varies significantly, with some more cost-effective than others. This variation underscores the importance of considering both cost and efficacy when selecting treatment options for ILD patients.

Table 5: Commonly Prescribed Drug Combinations for ILD Patients.

Drug Combination	Average Cost of Treatment/Prescription/ Month (Rs.)	FVC Baseline Mean ± SD	FVC Follow-Up	Average Improvement in FVC	ACER = Cost/ Average Increment in FVC
4 Combinations					
Steroid + Beta Agonist + Methylxanthine + Anticholinergic	2768	3.07 ± 0.86	3.82 ± 1.03	-0.75	3690
Steroid + Beta Agonist + Ambrisentan + Tadalafil	4755	3.17 ± 0.64	3.96 ± 0.97	-0.79	6018
Steroid + Methylxanthine + Acetylcysteine +	5320	3.37 ± 0.42	4.32 ± 1.09	-0.95	5600

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Nintedanib					
Antibiotic + Steroid + Methylxanthine + Nintedanib	5046	3.42 ± 1.20	4.17 ± 1.12	-0.75	6728
3 Combinations					
Steroid + Beta Agonist + Methylxanthine	1832	2.94 ± 0.34	3.36 ± 0.98	-0.42	4361
Steroid + Beta Agonist + Antibiotic	2260	3.01 ± 0.44	3.58 ± 0.67	-0.57	3964
Antibiotic + Methylxanthine + Nintedanib	3150	3.12 ± 0.28	3.76 ± 0.88	-0.64	4921
Antibiotic + Steroid + Methylxanthine	2366	3.42 ± 0.96	3.82 ± 1.02	-0.40	5915

DISCUSSION

The study of 84 participants presents a varied demographic profile. Most participants are aged between 31 and 60 years, with a slight majority in the 41-50 age range. There is a higher proportion of males compared to females, but this gender disparity does not significantly affect age distribution. Occupation-wise, homemakers and individuals exposed to dust are the most common, suggesting that these groups are central to the study's focus. Socio-economically, the largest group falls into the upper-lower category, with a varied representation across different socio-economic levels, reflecting a broad socio-economic spectrum. Smoking habits are also noteworthy which may influence health-related outcomes within the study.

This studyindicates that while Sarcoidosis and other rare or less well-defined ILDs are present, they are not as prevalent as Hypersensitivity Pneumonitis, Connective Tissue Disease-Associated ILD, and Idiopathic Pulmonary Fibrosis in this particular cohort. The high prevalence of Hypersensitivity Pneumonitis might reflect specific environmental or occupational exposures in the study population, which could be prevalent in the geographical or occupational settings represented [8,9].

The study's prescription patterns for respiratory health reveal a nuanced approach to treatment. Among single-drug prescriptions, Methylxanthines are the most commonly used. This suggests that they play a crucial role in managing respiratory conditions, likely due to their bronchodilator effects. Oral Corticosteroids follow closely, underscoring their importance in reducing inflammation and managing acute exacerbations in respiratory diseases. In the realm of Disease Modifying Pharmacological Interventions, Nintedanib is the most preferred medication. This preference suggests Nintedanib's effectiveness in managing specific interstitial lung diseases, possibly due to its targeted action against fibrotic processes. Regarding fixed-dose combinations, the **Inhaled Corticosteroid + Beta Agonist**combination is the most prevalent. This combination effectively reduces inflammation and provides bronchodilation, making it a cornerstone in managing chronic respiratory conditions [10].**Antibiotic Fixed Dose Combinations**, reflect an integrated strategy to manage infections alongside other treatments, improving patient outcomes by addressing potential bacterial complications. Overall, these prescription patterns indicate a broad and targeted approach to managing respiratory health, emphasizing the use of specific medications and combinations tailored to the diverse needs of patients.

The study's approach emphasizes a conservative, supportive care model with a focus on rehabilitation and ongoing patient support, minimizing the use of invasive procedures like lung transplantation and ventilation similar to other studies [11,12].

The K-BILD questionnaire data reveals a significant decline in patients' quality of life across all domains—Breathlessness and Activity, Chest Symptoms, and Psychological Impact—from baseline to follow-up. This decline is statistically significant, indicating a genuine and serious deterioration rather than random variation. These findings align with other research [13,14], highlighting the progressive nature of respiratory conditions and their impact on various aspects of patients' lives. The results underscore the need for comprehensive management strategies that address both the physical and psychological challenges of respiratory diseases to enhance patient outcomes and overall quality of life.

The study reveals that a substantial majority of the population demonstrates low to medium adherence levels. The predominance of low adherence highlights a critical area needing intervention. Addressing this issue could significantly improve therapeutic effectiveness and overall patient outcomes, emphasizing the importance of strategies to enhance medication adherence and ensure better management of the conditions.

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The cost minimization analysis reveals substantial price variability in both single drug prescriptions and fixed-dose combinations. For single drug prescriptions, **Methylxanthine** shows the highest cost variation at 150.20%, meaning its price can more than double depending on the supplier. Among fixed-dose combinations, **Fluticasone Propionate + Formoterol (MDI)** has the highest cost variation at 158.4%, showing a significant range in pricing. These findings align with other research [15,16]. These variations underscore the need for careful consideration of cost differences when selecting medications, as significant price discrepancies can impact the overall cost burden of treatment. Addressing and minimizing these cost variations could improve medication accessibility and reduce healthcare expenses, making treatment more affordable and equitable for patients.

In the present study, four-drug combinations generally cost more, ranging from Rs. 2768 to Rs. 5320 per month, but their cost-effectiveness varies. For example, the **Steroid + Beta Agonist + Methylxanthine + Anticholinergic** combination has a lower ACER (3690), indicating better cost-effectiveness compared to the **Steroid + Beta Agonist + Ambrisentan + Tadalafil** combination, which has a higher ACER (6018). Among three-drug combinations, **Steroid + Beta Agonist + Antibiotic** is the most cost-effective (ACER 3964), whereas **Antibiotic + Steroid + Methylxanthine** has a higher ACER (5915). These variations in ACER reflect differences in cost-effectiveness related to FVC improvements. Overall, the analysis emphasizes the need to balance cost and efficacy when selecting ILD treatments, as some combinations offer better value for money than others. Altaf et al. [17] focused on cost variations specific to the Indian healthcare setting. They found similar trends in cost-effectiveness, with three-drug combinations often being more cost-effective than more complex regimens. Their results aligned with the current study, which showed that combinations like **Steroid + Beta Agonist + Antibiotic** were among the most cost-effective options.

CONCLUSION

The study reveals important insights on the management and economics of respiratory disorders in a sample of 84 people. Key findings include a strong emphasis on hypersensitivity pneumonitis, showing particular environmental or occupational risk factors, and a prescription pattern that favours methylxanthines and oral corticosteroids for their efficacy in respiratory therapy. The study found significant cost differences in both single-drug prescriptions and fixed-dose combinations, with certain medication combinations being more cost-effective than others. Despite greater prices, four-drug combos such as steroids, beta-agonists, methylxanthine, and anticholinergics are more cost-effective than more expensive alternatives. The study emphasizes the significance of a holistic approach that balances cost and efficacy, emphasizes the need for better medication adherence, and recommends initiatives to address cost unpredictability in order to increase treatment accessibility and effectiveness. These findings are consistent with previous research and highlight the continuous need for personalized, cost-effective treatment solutions for ILD patients.

List of abbreviations

Interstitial Lung Disease: ILD);

Ethical Approval

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