Original Article

Evaluating the safety, tolerability, and efficacy of tulobuterol transdermal patch in patients with asthma or chronic obstructive pulmonary disease: A phase-IV clinical study

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ABSTRACT

BACKGROUND: Asthma and chronic obstructive pulmonary disease (COPD) contribute significantly to the global respiratory disease burden, with treatment adherence and nocturnal symptom control remaining key challenges. The Tulobuterol Transdermal Patch (Tuloplast™) provides continuous 24-h drug release, potentially improving adherence and symptom management. This Phase-IV clinical study evaluated its safety, tolerability, and efficacy in patients with asthma and COPD.

METHODS: This multicentric, open-label Phase-IV trial enrolled 300 patients (189 asthma, 111 COPD) across seven Indian centers. Patients received Tuloplast™ in age-appropriate doses for 4–6 weeks. Primary endpoints included safety and tolerability, assessed by adverse events, global ratings, and rescue medication use. Efficacy (secondary endpoint) was evaluated through symptom severity (GINA/GOLD criteria) and pulmonary function (peak expiratory flow [PEF], forced expiratory volume in 1 second [FEV_1], forced vital capacity [FVC]), with statistical significance determined using paired *t*-tests.

RESULTS: Only one patient (0.3%) reported an adverse event (mild swelling), with no serious safety concerns. At Day 28, 51.9% of asthma patients and 79.3% of COPD patients rated tolerability as "good," while 43.9% and 12.6%, respectively, rated it "excellent." Significant reductions in symptom severity were observed in asthma ($P < 0.0001$) and COPD patients ($P < 0.0001$), particularly for nocturnal symptoms (–74.88% for COPD, and –82.79% and –77.29% for pediatric and adolescent patients, respectively). Pulmonary function parameters (PEF, FEV_1, FVC) improved significantly in both groups ($P < 0.0001$).

CONCLUSION: Tuloplast™ demonstrated excellent safety, tolerability, and efficacy in improving symptom control and lung function. Its once-daily application enhances adherence, making it a promising alternative for asthma and COPD management.

KEYWORDS

Asthma, chronic obstructive pulmonary disease, transdermal patch, tulobuterol

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Background

Asthma and chronic obstructive pulmonary disease (COPD) are prevalent obstructive lung diseases characterized by variable or fixed expiratory airflow limitations.[1] These respiratory conditions

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pose a substantial global health burden, with COPD and asthma accounting for a significant proportion of chronic respiratory disease disability-adjusted life years (DALYs) worldwide. In India, COPD and asthma contribute to approximately 75.6% and 20% of chronic respiratory disease DALYs, respectively.[2] Despite considerable advancements in pharmacological interventions, challenges persist, including inadequate symptom control, nocturnal exacerbations, and poor patient adherence.

Inhaled corticosteroids (ICSs) form the foundation of asthma management, effectively targeting airway inflammation and hyperresponsiveness across varying severity levels. For patients with moderate-to-severe asthma, combining ICS with long-acting β2-adrenergic agonists improves symptom control.[3] However, the efficacy of inhalation therapy often diminishes due to suboptimal inhalation techniques, reduced inspiratory muscle strength, and adherence issues, especially among elderly and pediatric populations. Adherence to prescribed regimens is crucial for managing chronic diseases, as inadequate adherence compromises therapeutic outcomes and symptom control.[4,5]

One of the most challenging aspects of managing asthma and COPD is addressing nocturnal symptoms, including the "morning dip" phenomenon, where respiratory function markedly declines in the early morning hours. These symptoms not only disrupt sleep but also diminish patients' quality of life (QOL) and increase the burden on caregivers to address these challenges. Innovative therapeutic approaches are essential to optimize disease management.

Transdermal patches offer a promising alternative to conventional inhalation therapies, providing a noninvasive, continuous drug delivery method that maintains stable plasma levels over 24 h. The tulobuterol transdermal patch, introduced in Japan in 1998, has shown efficacy in maintaining consistent bronchodilation and minimizing nocturnal respiratory function decline. The patch's once-daily dosing and ease of application significantly enhance patient adherence compared to traditional inhalation devices.[4]

The safety and efficacy of tulobuterol transdermal patches have been well-documented in both pediatric and adult populations.[6-8] In India, the patch was approved by the Central Drugs Standards Control Organization (CDSCO) in May 2015 for the treatment of asthma and COPD in patients without comorbidities. Given the effective results from previous studies, a Phase IV clinical trial for Tuloplast™ (tulobuterol transdermal patches) has been initiated to evaluate further the safety, tolerability, and efficacy in patients diagnosed with asthma and COPD. This trial aims to generate real-world evidence on the effectiveness of this therapeutic modality, thereby addressing gaps in existing clinical data and informing future therapeutic strategies.

Materials and Methods

Study design

This was an open-label, single-arm, multicentric, Phase-IV clinical trial conducted to evaluate the safety, tolerability, and efficacy of the Tuloplast™ (Zuventus Healthcare Limited, India) in patients with asthma or COPD. The study was conducted across seven centres in India and included a total of 300 patients – 189 with asthma and 111 with COPD. The study was approved by the CDSCO and by the Institutional Ethics Committees of all participating centers.

The trial was prospectively registered with the Clinical Trial Registry of India (Registration No.: CTRI/2019/01/016974). The trial was conducted in compliance with the New Drugs and Clinical Trial Rules (2019), Ethical Guidelines laid by the Indian Council of Medical Research (2017), International Council on Harmonization Guidelines E6 (R2) for Good Clinical Practice (2016), and the Declaration of Helsinki principles (2013).

Study population

The study population consisted of patients diagnosed with asthma or COPD, selected based on predefined eligibility criteria. Asthma patients were categorized by age: Children under 6 years were required to have a physician's diagnosis with symptoms such as wheezing, coughing, shortness of breath, activity limitation, and nocturnal awakenings. Children aged 6–11 years needed similar criteria plus pulmonary function criteria (forced expiratory volume in 1 second [FEV_1]/forced vital capacity [FVC] <0.90) an increase in predicted FEV_1 of more than 12% from baseline, measured 10–15 min after inhaling 200–400 µg of salbutamol or an equivalent bronchodilator, as per GINA guidelines.

Patients aged 12 years and above were required to have similar symptoms with or without chest tightness, FEV_1/FVC <0.75 or bronchodilator reversibility, defined as an increase in FEV_1 of more than 12% and >200 mL from baseline, measured 10–15 min after 200–400 µg of salbutamol or an equivalent bronchodilator, along with evidence of uncontrolled asthma despite low-dose ICS therapy.

COPD patients were adults aged 40 years or older with stable disease, defined as post-bronchodilator FEV_1/FVC <0.70 as per GOLD guidelines, and symptoms such as dyspnea or chronic cough. Written informed

consent was obtained from all participants. For pediatric patients, parental consent was mandatory, including assent from children aged 6–11 years and adolescents.

Patients with a known hypersensitivity to the study medication, pulmonary infections, major organ disorders, severe comorbidities (e.g., cardiac diseases), recent history of smoking, acute exacerbations of asthma or COPD, comorbid respiratory diseases, major organ failure, or poorly controlled comorbidities were excluded. In addition, pregnant or breastfeeding women and patients deemed unsuitable for β2 agonist therapy were excluded from the study.

The exclusion criteria for the study were categorized based on age groups and underlying conditions. For children aged 6 months–11 years, patients with a known history of hypersensitivity to the study medication, dermatological diseases (including atopic dermatitis), or pulmonary infections were excluded. In addition, patients with major organ disorders such as liver or kidney failure, as well as those with poorly controlled associated diseases (including heart disease, hypertension, thyroid disorders, and diabetes), were not eligible for inclusion. Patients deemed inappropriate by the investigator, particularly those for whom treatment with β2 agonists was considered unsuitable, were also excluded.

For adolescent and adult asthma patients, exclusion criteria included a history of smoking within the 6 months preceding enrollment and acute exacerbation of asthma, with patients only being included after stabilization. Patients with dermatological diseases (including atopic dermatitis) or respiratory diseases other than asthma (such as emphysema, bronchiectasis, pulmonary fibrosis, lung cancer, or sarcoidosis) were not eligible. Furthermore, any existing pulmonary infection, severe illness requiring hospitalization, or known hypersensitivity to the study medication constituted grounds for exclusion. Patients with major organ disorders (like liver or kidney failure) or those with poorly controlled associated diseases, including heart disease, hypertension, thyroid disorders, and diabetes, were also excluded. Female patients who were pregnant, breastfeeding, or planning to become pregnant within 2 months of study initiation were not included. In addition, patients deemed inappropriate for the study by the investigator, particularly those for whom β2 agonist treatment was considered unsuitable, were excluded from participation.

Treatment protocol

Tuloplast™ (Zuventus Healthcare Limited) comprised transdermal patches and was available in strengths of 0.5 mg, 1.0 mg, and 2.0 mg. The patches were applied once daily to the chest, back, or upper arm. The treatment duration was 6 weeks for pediatric, adolescent, and adult asthma patients, including a 2-week run-in phase with maintenance therapy using ICS alone, followed by 4 weeks of study medication. COPD patients and asthma patients on ICS monotherapy received the patch for 4 weeks without a run-in period. Regular therapy (ICS for asthma and existing treatment for COPD) continued during the study, with inhaled short-acting beta agonists (SABA) permitted as rescue medication.

Study assessment

The primary outcomes were safety and tolerability, measured by the incidence of adverse events and global tolerability assessments by patients and investigators. Adverse events were classified according to severity (mild, moderate, severe) and causality, based on the WHO-UMC criteria. The tolerability of the patch was evaluated on Day 28 of the study using a 4-point scale (excellent, good, fair, or poor). This assessment was based on the feedback from both the investigator and the patient regarding their overall experience with the study medication.

Secondary outcomes included improvement in clinical symptoms and pulmonary function from baseline, assessed as per GINA 2018 and GOLD 2018 guidelines. Lung functions, FEV_1, Peak Expiratory Flow (PEF), and FVC were evaluated in triplicate using spirometry at baseline and on Days 1, 14, and 28, except in pediatric patients under 6 years of age, where impulse oscillometry was employed. For pediatric patients under 6 years of age, impulse oscillometry was performed at the same time points to evaluate respiratory impedance (Zrs). The measured parameters included resistance at 5 Hz (R5) and 20 Hz (R20), reactance at 5 Hz (X5), resonant frequency (Fres), and reactance area (Ax). As with spirometry, all impulse oscillometry measurements were taken in triplicate to ensure consistency.

Symptom assessment included wheezing, coughing, dyspnea, activity limitation, chest tightness, and nocturnal awakenings, graded on a 4-point scale to determine symptom severity and frequency.

Statistical analysis

Data were presented as mean ± standard deviation or percentages. Safety and tolerability were assessed using descriptive statistics. The difference in pulmonary function and symptom severity from baseline to the end of the study was analyzed using paired *t*-tests, with $P < 0.05$ considered statistically significant. Change in symptom scores and pulmonary function parameters were evaluated using repeated measures analysis of variance (ANOVA). The proportion of patients requiring rescue medication was also calculated, and

95% confidence intervals were used to interpret the true proportions.

Results

Patients characteristics

The study enrolled 300 patients presenting symptoms of Asthma or COPD, all of whom were screened and included in the study. Of these, 189 were diagnosed with Asthma, and 111 with COPD. None of the participants discontinued the study medication for any reason. The demographic characteristics of the patients are summarized in Table 1, with ages ranging from 2 to 69 years and a mean age of 37.8 ± 21.98 years.

Safety and tolerability

Only one patient (0.3%) reported an adverse event during the study period, specifically mild swelling around the neck, which was managed with antibiotics and NSAIDs. No other side effects were reported throughout the trial.

The global assessment on Day 28 by patients indicated that 51.90% rated tolerability as "good" and 43.90% as "excellent" for asthma, while 79.30% rated it as "good" and 12.60% as "excellent" for COPD. The overall tolerability assessment by both patients and investigators on Day 28 is represented in Figure 1.

Table 1: Demographics and other baseline characteristics.

Parameter	Asthma		COPD (*n*=111)
	Pediatric (*n*=80)	Adolescent and adult (*n*=109)	
Gender, *n* (%)			
Male	47 (58.75)	52 (47.7)	79 (71.2)
Female	33 (41.25)	57 (52.3)	32 (28.8)
Age (years)	7.3±1.87	42.5±14.67	55.2±9.92
Weight (kg)	22.6±4.82	59.7±10.07	60.8±10.73
Height (cm)	120.5±13.01	158.8±9.74	160.5±8.76
BMI (kg/m^2)	15.38±0.891	23.74±4.056	23.65±4.088

Data represented as *n* (%) or mean±SD. SD=Standard deviation, BMI=Body mass index, COPD=Chronic obstructive pulmonary disease

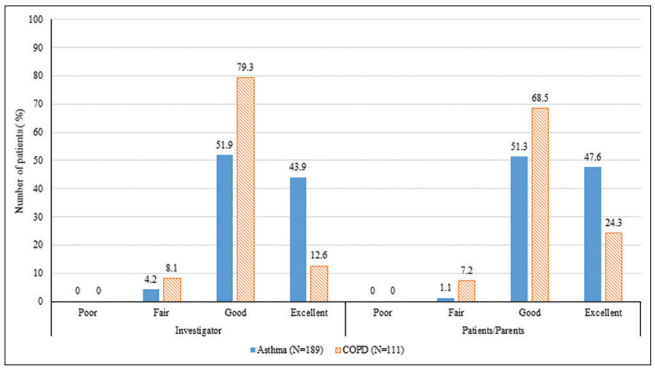

Figure 1: Tolerability assessment at day 28.

None of the patients reported a poor response toward treatment tolerability.

The percentage of asthma patients requiring rescue medication on Day 14 was 22.20%, which decreased to 16.40% by Day 28. In COPD patients, the need for rescue medication was 34.20% on Day 14 and 33.30% on Day 28. The percentage of patients requiring rescue medication is shown in Figure 2.

These findings suggest that Tuloplast™ is well-tolerated, with a safety profile comparable to existing long-acting bronchodilators. The reduction in rescue medication usage further highlights its potential in achieving sustained symptom control, reducing patient reliance on SABAs.

Efficacy

In pediatric asthma patients (n = 80) and adolescent/adult asthma patients (n = 109), significant reductions in clinical symptom severity scores were observed by Day 28 across all symptoms ($P < 0.0001$). Figure 3 illustrates the Clinical Symptoms Severity Score from Baseline to Day 28 in asthma patients, while Table 2 provides the statistical analysis of symptom reduction in both groups.

In the pediatric group, symptoms such as wheezing, cough, shortness of breath, nocturnal awakening, and chest tightness showed progressive reductions, with activity limitation completely resolved by Day 28 (–100%). In the adolescent/adult group, substantial reductions were noted by Day 14, particularly in nocturnal awakening and chest tightness. By Day 28, all symptoms, including wheezing, cough, shortness of breath, nocturnal awakening, and chest tightness, demonstrated significant improvements.

These findings indicate that the intervention effectively reduced the severity of asthma symptoms over time, with consistent and substantial improvements observed across all symptoms in both pediatric and adolescent/

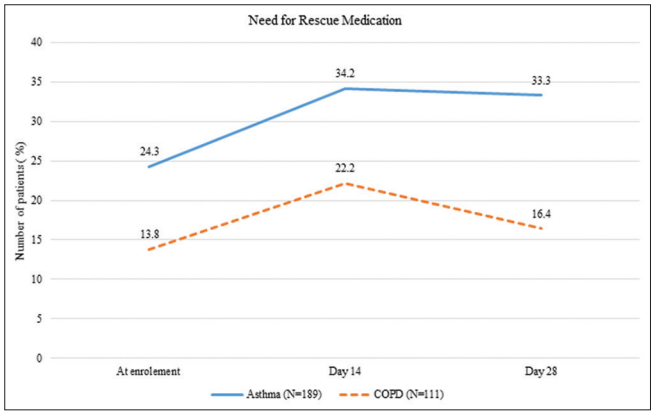

Figure 2: Assessment of need for rescue medication.

adult groups. By Day 28, none of the patients had severe symptom severity scores.

The COPD population also showed significant improvement in the clinical severity symptom score on Day 28 for all the symptoms ($P < 0.0001$). Nocturnal awakenings showed the greatest improvement (–74.88%), followed by cough (–51.06%), sputum production (–57.96%), and dyspnea (–59.31%). The Clinical Symptoms Severity Score from Baseline to Day 28 in COPD Patients is shown in Figure 4, and the statistical analysis of symptom reduction in COPD patients is given in Table 3. None of the patients had a severe severity symptom score on Day 28.

There was a significant improvement in pulmonary function parameters for both asthma and COPD patients by Day 28. In asthma patients, PEF increased slightly from baseline to Day 14 and further improved by Day 28, with significant mean differences observed at each time point ($P < 0.0001$). FEV_1 and FVC also showed progressive and significant increases by Day 14 and Day 28, highlighting consistent improvement in lung function ($P < 0.0001$).

Similarly, COPD patients experienced notable enhancements in PEF, FEV_1, and FVC. By Day 14, all three parameters showed statistically significant improvements compared to baseline, which further increased by Day 28. The mean differences for all parameters were highly significant ($P < 0.0001$) at each interval. Overall, the results indicate that the treatment led to substantial and sustained improvements in lung function for both asthma and COPD patients, with the greatest benefits observed by the end of the study at Day 28. Table 4 summarizes the improvements in pulmonary function parameters in asthma and COPD patients over the 28-day study period.

Repeated measures ANOVA was performed for all symptom parameters and pulmonary function

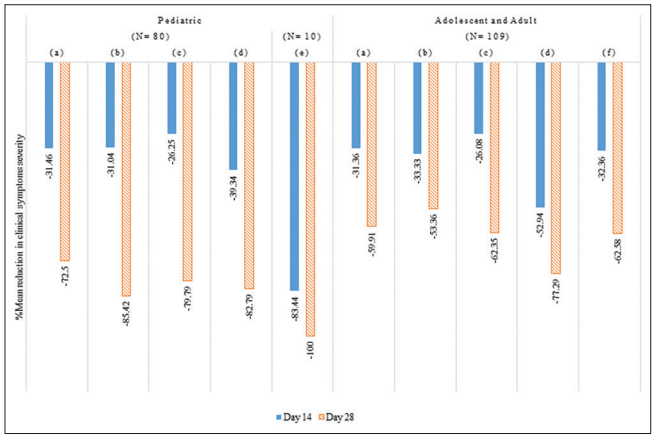

Figure 3: Reduction in clinical symptoms severity score from baseline to day 28 in asthma patients, depicting changes in individual symptom scores, including (a) Wheezing, (b) Cough, (c) Shortness of breath, (d) Nocturnal awakening, (e) Activity limitation, and (f) Chest tightness.

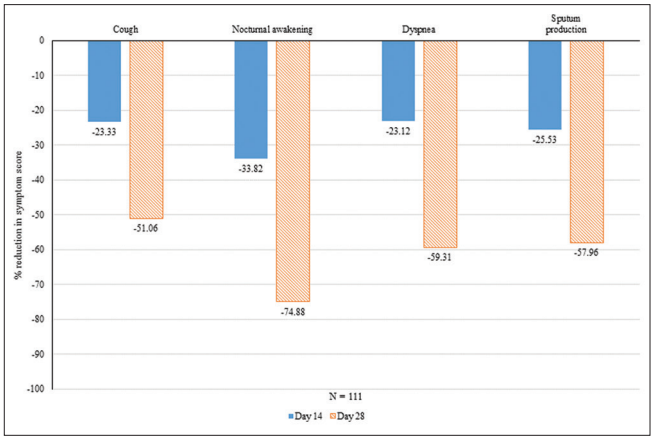

Figure 4: Clinical symptoms severity score from baseline to day 28 in chronic obstructive pulmonary disease patients.

Table 2: Statistical analysis of symptomatic improvement in pediatric, adolescent, adult patients with asthma.

Symptoms	Baseline, mean±SD	Day 14, mean±SD (percentage change)[a]	Day 28, mean±SD (percentage change)[a]	ANOVA (*P*)[b]		
				Baseline versus day 14	Day 14 versus Day 28	Baseline versus Day 28
Pediatric						
Wheezing (*n*=80)	2.17±0.47	1.49±0.53 (–31.46)	0.63±0.54 (–72.50)	<0.0001	<0.0001	<0.0001
Cough (*n*=80)	1.99±0.51	1.35±0.53 (–31.04)	0.31±0.47 (–85.42)	<0.0001	<0.0001	0.0005
Shortness of breath (*n*=80)	1.89±0.42	1.35±0.48 (–26.25)	0.39±0.49 (–79.79)	0.0004	<0.0001	0.0359
Nocturnal awakening (*n*=80)	1.54±0.50	0.95±0.62 (–39.34)	0.33±0.47 (–82.79)	<0.0001	<0.0001	<0.0001
Activity limitation (*n*=10)	1±0	0.17±0.41 (–83.33)	0±0 (–100)	0.5165	NA[c]	NA[c]
Adolescent and adult						
Wheezing (*n*=109)	1.74±0.54	1.18±0.70 (–31.92)	0.68±0.63 (–59.91)	<0.0001	<0.0001	<0.0001
Cough (*n*=109)	1.82±0.60	1.18±0.65 (–33.33)	0.82±0.65 (–53.36)	<0.0001	<0.0001	<0.0001
Chest tightness (*n*=109)	1.76±0.60	1.18±0.71 (–32.36)	0.67±0.65 (–62.58)	<0.0001	<0.0001	<0.0001
Shortness of breath (*n*=109)	1.73±0.48	1.25±0.64 (–26.08)	0.64±0.59 (–62.35)	<0.0001	<0.0001	<0.0001
Nocturnal awakening (*n*=109)	1.39±0.52	0.71±0.73 (–52.94)	0.33±0.50 (–77.29)	<0.0001	<0.0001	<0.0001

[a]Statistically significant percentage reduction in symptoms was observed at day 14 and day 28 compared to baseline (P<0.0001), [b]Repeated measures ANOVA was used to compare the mean symptom scores across different visits, [c]Insufficient data to calculate *P* value. SD=Standard deviation, ANOVA=Analysis of variance

Table 3: Statistical analysis of symptomatic improvement in patients with chronic obstructive pulmonary disease.

Symptoms	Baseline, mean±SD	Day 14, mean±SD (percentage change)[a]	Day 28, mean±SD (percentage change)[a]	ANOVA (*P*)[b]		
				Baseline versus day 14	Day 14 versus day 28	Baseline versus day 28
Cough (*n*=111)	2.14±0.64	1.62±0.72 (−23.33)	1.00±0.65 (−51.06)	<0.0001	<0.0001	0.0002
Nocturnal awakening (*n*=111)	1.74±0.58	1.14±0.65 (−33.82)	0.48±0.63 (−74.88)	<0.0001	<0.0001	<0.0001
Dyspnea (*n*=111)	1.97±0.46	1.50±0.60 (−23.12)	0.82±0.57 (−59.31)	<0.0001	<0.0001	<0.0001
Sputum production (*n*=111)	1.83±0.64	1.35±0.70 (−25.53)	0.73±0.62 (−57.96)	<0.0001	<0.0001	0.0008

[a]Statistically significant percentage reduction in symptoms was observed at day 14 and day 28 compared to baseline (P<0.0001), [b]Repeated measures ANOVA was used to compare the mean symptom scores across different visits. SD=Standard deviation, ANOVA=Analysis of variance

Table 4: Improvement in pulmonary function parameters in asthma and chronic obstructive pulmonary disease patients over 28 days.

Parameter	Baseline, mean±SD	Day 14, mean±SD	Day 28, mean±SD	*P*[a]
Asthma (*n*=137)				
PEF (L/s)	2.64±1.40	2.67±1.59	2.64±1.40	<0.0001
FEV_1 (L)	1.43±0.51	1.46±0.47	1.57±0.47	<0.0001
FVC (L)	2.19±0.61	2.19±0.60	2.29±0.58	<0.0001
COPD (*n*=109)				
PEF (L/s)	2.45±1.54	2.55±1.51	2.54±1.39	<0.0001
FEV_1 (L)	1.21±0.38	1.36±0.38	1.45±0.39	<0.0001
FVC (L)	1.84±0.56	2.04±0.60	2.10±0.60	<0.0001

[a]Repeated measures ANOVA was used to compare the mean pulmonary function parameters across different visits in asthma and COPD patients. SD=Standard deviation, COPD=Chronic obstructive pulmonary disease, FVC=Forced vital capacity, PEF=Peak expiratory flow, FEV_1=Forced expiratory volume in 1 s

parameters, and a statistically significant change over time (from baseline to Day 28) was observed in both asthma and COPD patients [Tables 2-4].

Discussion

Tulobuterol patch offers several advantages over traditional inhalation therapies, particularly in terms of patient adherence and convenience. The once-daily application of the patch addresses one of the primary barriers to adherence – frequency of administration – thereby improving compliance and overall treatment outcome.[9] This is particularly important in chronic conditions like asthma and COPD, where consistent medication use is crucial for effective disease management.

In clinical trials, the tulobuterol patch has demonstrated significant improvements in pulmonary function and symptom control. A study conducted by Inoue *et al*. in 2017[10] on patients with asthma showed that the patch is effective as an add-on therapy to ICSs, enhancing lung function and reducing airway inflammation markers. In patients with COPD, the patch has been shown to improve QOL and reduce the frequency of exacerbations, with a safety profile comparable to other long-acting bronchodilators. Additionally, it has proven to be as effective as or better than inhaled long-acting β2-agonists. Compared to systemic delivery methods, such as oral sustained-release β_2-agonists, tulobuterol has demonstrated similar or superior improvements in FEV_1 and nocturnal symptoms, accompanied by fewer systemic side effects.[8,11] Data from this Phase IV clinical trial further corroborate these findings, showing significant reductions in clinical symptom severity scores across the entire study period. Significant reductions in symptom severity were observed in asthma ($P < 0.0001$) and COPD patients ($P < 0.0001$), particularly for nocturnal symptoms by Day 28. Substantial improvements were also observed in pulmonary function parameters. PEF and FEV_1 improved significantly in both asthma and COPD patients by Day 28 ($P < 0.0001$), with greater gains in COPD patients. FVC also improved significantly, with asthma patients showing slightly better gains, while COPD patients had a lower baseline FVC, consistent with their disease pathology. These findings highlight the patch's effectiveness in enhancing symptom control and pulmonary function across various patient populations.

One of the standout features of the Tuloplast™ patch is its transdermal delivery system. Unlike inhalation therapies, which require proper technique and adherence, the patch provides a convenient, once-daily alternative that ensures consistent drug delivery over 24 h. This is particularly advantageous for patients who struggle with inhaler use or demonstrate poor adherence to inhaled therapies.[4] By eliminating the technical complexities associated with inhalation devices, the patch simplifies treatment and may enhance overall adherence rates.[12] Its ease of use makes it particularly well-suited for elderly and pediatric populations, who often face challenges with inhalation techniques.

The tulobuterol patch's favorable safety profile further enhances its appeal. By providing a steady release of medication, the patch avoids the peaks and troughs in drug concentration often associated with oral or inhaled therapies, thereby minimizing systemic side effects such as cardiovascular complications which are often a concern with β2-agonists.[4] In this clinical trial, adverse events were minimal, with only one case of mild swelling reported. The majority of patients rated the patch's tolerability as "good" or "excellent," highlighting its

suitability for long-term use. This makes it an excellent choice for patients with comorbid conditions where systemic drug exposure could pose risks.

Another advantage of the tulobuterol patch is its continuous, low-level delivery, which unlike intermittent high-dose β-agonist exposure that drives receptor phosphorylation and internalization, preserves β-adrenoceptor responsiveness. Kume *et al*. showed that chronic low-concentration tulobuterol exposure does not attenuate airway smooth muscle relaxation.[13] This makes the patch well-suited for long-term management of asthma and COPD.

The tulobuterol transdermal patch's unique delivery system, along with its established efficacy and safety, makes it a compelling choice for both patients and healthcare providers. As more data become available, the role of the tulobuterol patch in respiratory care is likely to expand, offering new possibilities for improving patient outcomes in these challenging conditions. This aligns with the growing emphasis on personalized medicine and patient-centered care in chronic disease management.

The current open-label, single-arm study design lacks a placebo or active comparator, which may introduce expectation and observer biases. In addition, the 4–6-week duration limits assessment of long-term safety, tolerability, and efficacy. Therefore, future randomized controlled trials over extended periods are warranted to establish the durability of benefits and a comprehensive safety profile.

Conclusion

Tulobuterol transdermal patch represents a significant advancement in the treatment of asthma and COPD in both pediatric and adult populations. Its unique attributes – including ease of use, improved adherence, and a favorable safety profile – address key limitations of traditional therapies. The comprehensive benefits observed in both objective lung function metrics and subjective QOL indicators underscore its potential as a cornerstone therapy in respiratory care. Future studies could explore long-term outcomes and compare the efficacy of patches with other standard treatments to further validate these findings.

Authors' contributions

BD contributed to the concepts, design, definition of intellectual content, clinical studies, data analysis, statistical analysis, manuscript review, and acted as a guarantor. SS contributed to the design, literature search, clinical studies, data acquisition, data analysis, statistical analysis, and manuscript editing. RG contributed to literature search, data analysis, statistical analysis, manuscript preparation, and manuscript editing.

Ethical statement

The study was approved by the CDSCO, India and all Institutional Ethics Committees of the study centre. The trial was conducted in compliance with the Guidelines for Good Clinical Practice, and the Declaration of Helsinki principles.

Data availability statement

Data are accessible from the corresponding author upon request.

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Patient consent

The written informed consent was obtained from all patients for this study.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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