



COMPARATIVE EVALUATION OF THE EFFECTS OF INHALED BUDESONIDE AND FLUTICASONE PROPIONATE ON SERUM CORTISOL LEVELS AS A MARKER OF ADRENAL SUPPRESSION IN ADULTS WITH MODERATE PERSISTENT ASTHMA: A RANDOMIZED PILOT STUDY

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ABSTRACT

Background: Inhaled corticosteroids (ICS) are the cornerstone of long-term asthma management because of their potent anti-inflammatory effects and ability to reduce exacerbations. Despite their favorable safety profile compared with systemic corticosteroids, prolonged or high-dose ICS therapy may result in systemic adverse effects, including hypothalamic-pituitary-adrenal (HPA) axis suppression. Budesonide and fluticasone propionate differ in pharmacokinetic and pharmacodynamic properties that may influence their potential for adrenal suppression; however, comparative evidence in Indian adults with asthma remains limited.

Objective: To compare the short-term effects of inhaled budesonide and fluticasone propionate on serum cortisol levels, pulmonary function, and asthma-related quality of life in adults with moderate persistent asthma.

Methods: This prospective randomized pilot study was conducted in the Department of Respiratory Medicine at a tertiary care hospital. The study enrolled 32 adults with moderate persistent asthma who were allocated in a 1:1 ratio to receive either inhaled budesonide (400 µg/day; $n = 16$) or fluticasone propionate (500 µg/day; $n = 16$) for 15 days. Morning fasting serum cortisol concentrations were measured at baseline and post-treatment as the primary outcome. Secondary outcomes included pulmonary function parameters (forced expiratory volume in one second [FEV₁], forced vital capacity [FVC], and peak expiratory flow rate [PEFR]) and Asthma Quality of Life Questionnaire (AQLQ) scores. Continuous variables were analyzed using paired and independent-samples t -tests, with effect sizes expressed as Cohen's d . Statistical significance was established at $p < 0.05$.

Results: Both treatment groups demonstrated reductions in serum cortisol levels after 15 days of therapy. The mean reduction was numerically greater in the fluticasone propionate group compared to the budesonide group (-52.76 ± 81.2 nmol/L versus -34.54 ± 65.1 nmol/L; $p < 0.001$; Cohen's $d = 0.82$). Improvements in AQLQ scores were observed in

both groups (Budesonide & Fluticasone, $+0.36 \pm 0.02$ and $+0.34 \pm 0.01$, $p = 0.001$), while pulmonary function parameters remained comparable throughout the study period.

Conclusion: Short-term treatment with inhaled budesonide and fluticasone propionate improved asthma-related quality of life while producing measurable reductions in serum cortisol concentrations. Fluticasone propionate was associated with a greater decline in serum cortisol than budesonide under the investigated dosing regimen, indicating a potential for greater systemic corticosteroid exposure. The observed differences should be interpreted cautiously given the pilot nature, short duration, and dose differences between treatment groups. Larger, long-term studies incorporating dynamic endocrine testing are required to confirm these findings and guide optimal ICS selection.

KEYWORDS: Asthma, Inhaled Corticosteroids, Serum Cortisol, Adrenal Suppression, Quality of Life.

Introduction

Asthma is a heterogeneous chronic inflammatory disease of the airways characterized by variable respiratory symptoms, including wheezing, breathlessness, chest tightness, and cough, accompanied by variable expiratory airflow limitation. It remains one of the most prevalent chronic respiratory disorders worldwide, affecting more than 260 million individuals and contributing substantially to morbidity, healthcare utilization, and reduced quality of life despite advances in pharmacological management[1–3]. Persistent airway inflammation and recurrent exacerbations can lead to progressive airway remodeling and impaired pulmonary function, indicating the importance of effective long-term disease control[4,5].

Current international guidelines, including those of the Global Initiative for Asthma (GINA), recommend inhaled corticosteroids (ICS) as the cornerstone of controller therapy for patients with persistent asthma because of their well-established efficacy in suppressing airway inflammation, improving lung function, reducing symptom burden, and preventing exacerbations[6]. Regular ICS therapy has significantly improved asthma outcomes and reduced the need for systemic corticosteroids, thereby minimizing treatment-related morbidity[7]. Among the available ICS formulations, budesonide and fluticasone propionate are widely prescribed owing to their potent anti-inflammatory effects and favorable therapeutic efficacy. However, these agents differ in pharmacokinetic and pharmacodynamic characteristics, including glucocorticoid receptor affinity, pulmonary residence time, oral bioavailability, lipophilicity, and systemic clearance, which may influence their systemic safety profiles[8,9].

Although inhaled corticosteroids are generally associated with fewer systemic adverse effects than oral corticosteroids, systemic absorption may occur, particularly with prolonged treatment, higher doses, or formulations possessing greater systemic potency. One of the most clinically relevant systemic complications is suppression of the hypothalamic–pituitary–adrenal (HPA) axis, which may reduce endogenous cortisol production and, in severe cases, predispose patients to adrenal insufficiency[10]. While clinically significant adrenal suppression is uncommon with conventional ICS doses, the risk increases with higher cumulative exposure

and may remain unrecognized because of its frequently asymptomatic presentation[11]. Consequently, identifying inhaled corticosteroids that provide effective asthma control while minimizing systemic endocrine effects remains an important consideration in optimizing long-term therapy.

Several studies have compared the systemic effects of budesonide and fluticasone propionate, with evidence suggesting that fluticasone propionate may exert greater adrenal suppressive effects because of its higher glucocorticoid receptor affinity and prolonged pulmonary retention[12–15]. However, published findings remain inconsistent, partly owing to variations in study populations, corticosteroid doses, treatment duration, and methods used to assess adrenal function.

Serum cortisol concentration is a practical and widely used biochemical marker for evaluating adrenal function and serves as an indicator of potential HPA axis suppression associated with corticosteroid therapy. Although basal morning serum cortisol measurement does not replace dynamic endocrine testing, it provides a feasible and clinically relevant screening tool for detecting early alterations in adrenal function, particularly in short-term clinical studies[16]. When interpreted alongside pulmonary function tests and validated patient-reported outcome measures such as the Asthma Quality of Life Questionnaire (AQLQ), serum cortisol assessment offers a broader understanding of the overall benefit-risk profile of inhaled corticosteroid therapy.

Therefore, this randomized pilot study compared the short-term effects of inhaled budesonide and fluticasone propionate on serum cortisol levels, pulmonary function, and asthma-related quality of life in adults with moderate persistent asthma.

Materials and Methods

Study Design and Settings

This prospective, randomized, comparative pilot study was conducted in the Department of Respiratory Medicine and Tuberculosis, NIMS University Rajasthan, Jaipur, India, between November 2022 and April 2023. The study was designed to compare the short-term effects of inhaled budesonide and fluticasone propionate on adrenal function, pulmonary function, and asthma-related quality of life in

adults with moderate persistent asthma. The study protocol was approved by the Institutional Ethics Committee of NIMS University Rajasthan (Approval No. NIMSUR/IEC/2022/353; approval date: 16 September 2022) and was conducted in accordance with the ethical principles of the Declaration of Helsinki. Written informed consent was obtained from all participants before enrolment.

Study Participants

Adults aged 18–70 years with a confirmed diagnosis of moderate persistent asthma according to the Global Initiative for Asthma (GINA) guidelines were screened for eligibility. Eligible participants included both males and females who had not received oral or systemic corticosteroids within seven days before enrolment and were willing to provide written informed consent. Patients were excluded if they were pregnant or breastfeeding or had a history of autoimmune diseases, endocrine disorders affecting adrenal function, lung malignancy, or any medical condition that could interfere with study outcomes.

Study Sample

A total of 32 adult asthmatic patients were recruited based on feasibility and statistical justification for a pilot study design. The sample size was justified based on pilot study standards, assuming an effect size of 0.8, a 95% confidence level, and a 5% margin of error. Given the limited study duration and available eligible patients, a total of 32 participants (16 per treatment group) was both statistically adequate and practically achievable. All 32 participants completed the study, and their data were included in the final analysis. No participants were lost to follow-up or withdrew during the 15-day assessment period. Assessments were conducted at two time points: baseline (day 0) and post-treatment (day 15). No interim evaluations were performed between these visits.

Randomization and Allocation

Participants were randomly assigned in a 1:1 ratio to receive either inhaled budesonide or inhaled fluticasone propionate using a computer-generated randomization sequence prepared by an independent investigator who was not involved in participant recruitment or outcome assessment. Sixteen participants were allocated to each treatment group. Owing to the nature of the intervention, blinding was not performed.

Data Collection Tools

Clinical and demographic information was documented using a structured case record form developed for the study. The following standardized instruments were used:

- Inhaled budesonide (400 µg/day)
- Inhaled fluticasone propionate (500 µg/day)
- Portable digital spirometer
- Peak flow meter
- Serum cortisol assay kit

- Asthma Quality of Life Questionnaire (AQLQ)

All equipment was calibrated and maintained according to institutional quality assurance procedures.

Intervention

Participants received one of the following inhaled corticosteroid regimens for 15 consecutive days: Budesonide: 400 µg/day and Fluticasone propionate: 500 µg/day. The prescribed doses reflected routine clinical practice for patients with moderate persistent asthma. Participants were instructed regarding the correct inhaler technique before initiating treatment. Medication adherence and symptom progression were assessed during follow-up through patient interviews. Because budesonide and fluticasone propionate differ in pharmacological potency and systemic bioavailability, the administered doses should not be considered pharmacologically equivalent. This difference was taken into consideration during interpretation of the study findings.

Outcome Measures

The primary outcome was the change in morning serum cortisol concentration from baseline to Day 15 as a biochemical marker of adrenal function. The secondary outcomes included changes in pulmonary function parameters and asthma-related quality of life.

Pulmonary function was assessed using: Forced expiratory volume in one second (FEV₁), Forced vital capacity (FVC), and Peak expiratory flow rate (PEFR). Asthma-related quality of life was evaluated using the validated Asthma Quality of Life Questionnaire (AQLQ).

Pulmonary Function Assessment

Pulmonary function testing was performed at baseline and after 15 days using a calibrated portable digital spirometer in accordance with the American Thoracic Society/European Respiratory Society (ATS/ERS) recommendations. Participants performed the tests in the seated position using disposable mouthpieces following standardized instructions. Three technically acceptable manoeuvres were obtained for each participant, and the highest recorded value was used for statistical analysis. The spirometer was calibrated daily using a 3-L calibration syringe according to the manufacturer's recommendations. Environmental conditions were maintained consistently throughout the study to minimize measurement variability.

Study Procedures

Baseline assessments were performed before initiation of inhaled corticosteroid therapy. Demographic characteristics, clinical history, anthropometric measurements, pulmonary function, serum cortisol concentrations, and AQLQ scores were recorded using a standardized case record form. Morning fasting venous blood samples for serum cortisol estimation were collected between 08:00 and 09:00 hours to minimize the effects of diurnal variation. Serum cortisol

concentrations were measured using standardized laboratory procedures.

Following baseline evaluation, participants received the allocated inhaled corticosteroid therapy for 15 days. At the end of the treatment period, all baseline assessments, including serum cortisol estimation, pulmonary function testing, and AQLQ evaluation, were repeated using identical procedures.

Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics version 22.0 (IBM Corp., Armonk, NY, USA) and GraphPad Prism software. Continuous variables were assessed for normality using the Shapiro–Wilk test and are presented as mean $\pm$ standard deviation (SD). Baseline demographic characteristics were summarized using descriptive statistics. Within-group comparisons between baseline and post-treatment values were performed using paired-samples *t*-tests, whereas between-group comparisons were conducted using independent-samples *t*-tests. Effect sizes were calculated using Cohen's *d* and interpreted as small (0.2), medium (0.5), or large (≥ 0.8). Mean differences are presented with 95% confidence intervals (95% CI) where appropriate. All participants completed the study;

therefore, no missing data or imputation procedures were required. A two-tailed *p*-value of <0.05 was considered statistically significant.

Results

A total of 32 patients were enrolled and evenly randomized into two groups: Budesonide ($n = 16$) and Fluticasone Propionate ($n = 16$). The mean age of participants was 38.87 ± 15.78 years in the Budesonide group and 43.81 ± 18.50 years in the Fluticasone group, with no statistically significant difference between the two groups ($p = 0.42$). Baseline height and weight were also comparable between the groups, with mean heights of 167.10 ± 8.61 cm for Budesonide and 163.50 ± 6.57 cm for Fluticasone ($p = 0.18$), and mean weights of 56.12 ± 14.05 kg and 58.18 ± 16.37 kg, respectively ($p = 0.70$). The effect sizes were small to negligible, confirming adequate baseline similarity (Table 1).

At baseline, serum cortisol levels were similar between the two groups (Budesonide: 306.26 ± 45.83 nmol/L; Fluticasone: 311.85 ± 58.80 nmol/L; $p = 0.76$). Following 15 days of treatment, cortisol levels declined in both groups, with a more pronounced reduction observed in the Fluticasone group (Budesonide: 271.72 ± 46.12 nmol/L; Fluticasone: 259.09 ± 56.00 nmol/L).

Table 1: Demographic and Baseline Characteristics of Participants

Parameter	Budesonide (N=16)	Fluticasone (N=16)	Mean Difference (95% CI)	p-value	Effect Size (d)
Age (years)	38.87 ± 15.78	43.81 ± 18.50	$-4.94 (-17.5, 7.6)$	0.42	0.29
Height (cm)	167.10 ± 8.61	163.50 ± 6.57	$3.60 (-1.8, 8.9)$	0.18	0.47
Weight (kg)	56.12 ± 14.05	58.18 ± 16.37	$-2.06 (-13.5, 9.3)$	0.70	0.13
Gender (M/F)	Data available	Data available	—	0.47†	—

Values are presented as mean $\pm$ Standard Deviation; CI = confidence interval; †Chi-square test.

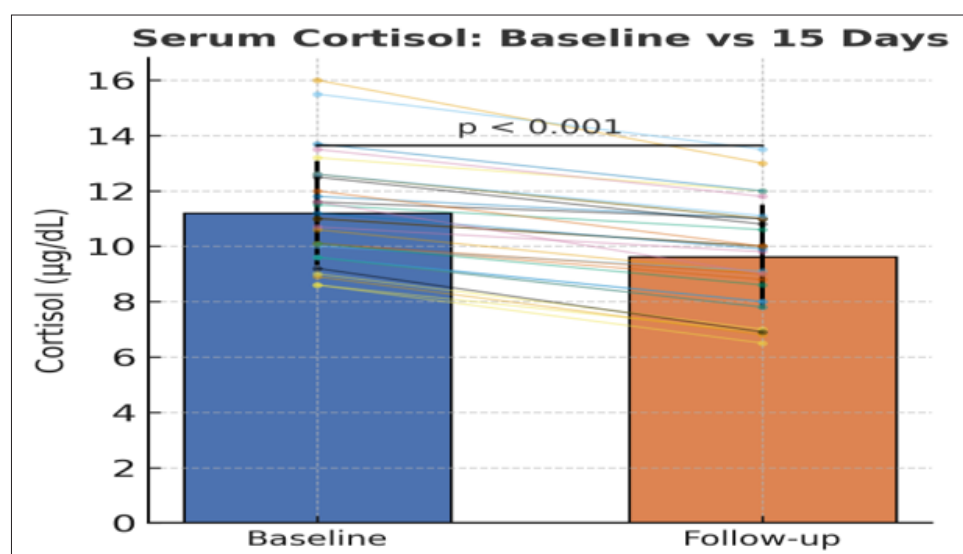


Figure 1. Comparison of mean serum cortisol reduction between fluticasone and budesonide groups

Table 2: Serum Cortisol Levels Before and After Treatment

Parameter	Budesonide (n = 16)	Fluticasone (n = 16)	t (30)	p-value	Effect Size (d)
Cortisol at Baseline	306.26 ± 45.83	311.85 ± 58.80	-0.30	0.76	0.10
Cortisol at Day 15 (Absolute value)	271.72 ± 46.12	259.09 ± 56.00	0.70	0.50	0.24
Change in cortisol on Day 15 from Baseline	-34.54 ± 65.1	-52.76 ± 81.2	4.32	< 0.001	0.82

Values are mean ± standard deviation (SD). Negative values indicate a reduction from baseline, *t* (30) = Student's *t* statistic with 30 degrees of freedom.

The mean change in cortisol from baseline to day 15 was -34.54 ± 65.1 nmol/L for Budesonide and -52.76 ± 81.2 nmol/L for Fluticasone. This difference was statistically significant ($p < 0.001$), with a large effect size (Cohen's $d = 0.82$), indicating greater adrenal suppression with Fluticasone. Figure 1 illustrates comparison of mean serum cortisol reduction between both the drugs and table 2 summarizes the cortisol data.

Asthma Quality of Life Questionnaire (AQLQ)

Baseline AQLQ scores were slightly higher in the Fluticasone group (3.73 ± 0.23) compared to the Budesonide group (3.46 ± 0.39), with a statistically significant difference ($p = 0.023$). After two weeks of treatment, both groups showed improvement in AQLQ scores (Budesonide: 3.84 ± 0.41 ; Fluticasone: 4.07 ± 0.24). The mean improvement from baseline was 0.36 ± 0.02 in the Budesonide group and 0.34 ± 0.01 in the Fluticasone group, indicating clinically meaningful improvement in both, though the difference was modest ($p = 0.001$) (Table 3).

Table 3: Asthma Quality of Life Questionnaire (AQLQ) Scores

Parameter	Budesonide (n = 16)	Fluticasone (n = 16)	t (30)	p-value	Effect Size (d)
AQLQ at baseline (pre-treatment)	3.46 ± 0.39	3.73 ± 0.23	-2.39	0.023	0.77
AQLQ after 2 weeks	3.84 ± 0.41	4.07 ± 0.24	-1.94	0.06	0.66
Change in AQLQ after Week 2 from Baseline)	0.36 ± 0.02	0.34 ± 0.01	3.58	0.001	0.93

($p < 0.001 \rightarrow$ statistically significant) AQLQ = Asthma Quality of Life Questionnaire; SD = standard deviation.

Table 4: Pulmonary Function Parameters at Baseline and Day 15

Parameter	Time Point	Budesonide (n = 16)	Fluticasone (n = 16)	*p*-value*	Effect Size (d)
FEV ₁ (L)	Baseline	2.58 ± 0.71	2.39 ± 0.60	0.42	0.29
	Day 15	2.71 ± 0.69	2.52 ± 0.58	0.38	0.30
	Change	+0.13 ± 0.04	+0.13 ± 0.03	0.88	0.04
FVC (L)	Baseline	3.26 ± 0.67	2.88 ± 0.58	0.09	0.61
	Day 15	3.38 ± 0.65	3.01 ± 0.56	0.08	0.62
	Change	+0.12 ± 0.03	+0.13 ± 0.04	0.70	0.09
PEFR (L/min)	Baseline	55.93 ± 21.38	54.43 ± 19.94	0.83	0.07
	Day 15	58.56 ± 20.12	57.18 ± 18.76	0.79	0.08
	Change	+2.63 ± 1.51	+2.75 ± 1.42	0.82	0.06

*Values are mean ± standard deviation; *p*-value for between-group comparison at each time point (unpaired *t*-test). FEV₁ = forced expiratory volume in one second; FVC = forced vital capacity; PEFR = peak expiratory flow rate.

Pulmonary function parameters, including FEV₁, FVC, and PEFR, were assessed at baseline and following 15 days of treatment. Both groups demonstrated modest improvements in all parameters; however, these changes were not statistically significant within or between groups. Mean FEV₁ improved from 2.58 ± 0.71 L to 2.71 ± 0.69 L in the budesonide group and from 2.39 ± 0.60 L to 2.52 ± 0.58 L in the fluticasone group (between-group $p = 0.38$). Similarly, FVC improved from 3.26 ± 0.67 L to 3.38 ± 0.65 L and from 2.88 ± 0.58 L to 3.01 ± 0.56 L, respectively (between-group $p = 0.08$). PEFR showed marginal improvements in both groups (budesonide: 55.93 ± 21.38 to 58.56 ± 20.12 L/min; fluticasone: 54.43 ± 19.94 to 57.18 ± 18.76 L/min; between-group $p = 0.79$) (Table 4).

Discussion

The present randomized pilot study compared the short-term effects of inhaled budesonide and fluticasone propionate on morning serum cortisol concentrations and asthma-related quality of life in adults with moderate persistent asthma. Both inhaled corticosteroids were associated with reductions in serum cortisol concentrations after 15 days of treatment and improvements in asthma-related quality of life. Notably, participants receiving fluticasone propionate exhibited a greater reduction in serum cortisol than those receiving budesonide, whereas improvements in quality-of-life scores were observed in both treatment groups. Baseline pulmonary function parameters were comparable between groups, indicating that differences in disease severity were unlikely to have influenced the observed endocrine outcomes.

Both the groups showed reduced serum cortisol levels after two weeks, confirming systemic absorption and hypothalamic–pituitary–adrenal (HPA) axis suppression, a recognized risk of corticosteroid therapy. However, the decline in cortisol was significantly greater in the fluticasone group compared to the budesonide group, indicating a stronger adrenal suppressive effect.

This finding aligns with previous pharmacodynamic studies showing fluticasone's higher glucocorticoid receptor affinity and longer pulmonary residence time, leading to greater systemic potency[9,10,16]. These properties, while beneficial for local anti-inflammatory efficacy, may contribute to increased systemic exposure and adrenal suppression. The large effect size (Cohen's $d = 0.82$) in our study reinforces the clinical significance of this difference, even within the short follow-up period.

Improvement in Asthma Quality of Life Questionnaire (AQLQ) scores was observed in both groups, suggesting that both ICS formulations effectively improved patient-reported outcomes such as symptom relief, emotional well-being, and daily activity performance. Although mean improvement was marginally higher with budesonide (0.36 vs. 0.34), the difference was minimal, indicating comparable clinical benefits. These findings support the notion that budesonide

and fluticasone provide comparable symptomatic control, consistent with existing literature[11,12]. The observed improvement is also consistent with prior studies validating the AQLQ as a sensitive and reliable tool for assessing asthma-related quality-of-life changes[17,18]. The modest baseline imbalance in AQLQ scores, with higher pre-treatment values in the fluticasone group, should be considered when interpreting post-treatment improvements. This difference suggests that participants in the fluticasone arm may have had slightly better initial asthma control or symptom perception, which could partially influence observed treatment-related gains in quality-of-life scores.

Baseline and post-treatment pulmonary function parameters including, forced expiratory volume in one second (FEV₁), forced vital capacity (FVC), and peak expiratory flow rate (PEFR) remained comparable between the two groups. Both treatments maintained stable lung function, reinforcing their established efficacy in asthma management.

No significant intergroup differences were found, consistent with previous trials showing equivalent bronchodilatory and anti-inflammatory performance of budesonide and fluticasone at clinically equivalent doses[11,12]. It should be noted that baseline FVC values were slightly higher in the budesonide group, though not statistically significant. This subtle difference may reflect inter-individual variability in lung capacity rather than a true treatment-related disparity, but it warrants consideration when interpreting comparative outcomes.

The clinical interpretation of these findings emphasizes the importance of balancing therapeutic efficacy with systemic safety. While both inhaled corticosteroids achieved meaningful improvement in asthma control, the greater cortisol suppression associated with fluticasone underscores the need for careful dose titration and monitoring of adrenal function, especially during prolonged therapy.

In contrast, budesonide exhibited a comparatively safer adrenal profile, making it a potentially preferred option for patients requiring long-term corticosteroid maintenance or those at higher risk of systemic adverse effects.

Limitations

This study has several limitations. First, the sample size was small, as the study was designed as a pilot investigation, which limits the generalizability of the findings. Second, the duration of follow-up was short and may not reflect long-term endocrine or clinical outcomes. Additionally, the doses of inhaled corticosteroids used were not pharmacologically equivalent; therefore, differences in serum cortisol reduction and potential adrenal suppression may reflect dose potency rather than intrinsic differences in drug safety. Finally, adrenal function was assessed using basal serum cortisol levels without dynamic endocrine testing, which limits definitive conclusions regarding hypothalamic–pituitary–adrenal axis suppression.

Conclusion

This randomized pilot study demonstrated that both inhaled budesonide and fluticasone propionate were associated with reductions in morning serum cortisol concentrations and improvements in asthma-related quality of life in adults with moderate persistent asthma. Fluticasone propionate produced a greater reduction in serum cortisol than budesonide under the investigated dosing regimen, suggesting comparatively greater systemic glucocorticoid exposure. However, these findings should be interpreted cautiously because of the pilot design, small sample size, short treatment duration, and non-equivalent corticosteroid doses.

Additional Information

Disclosures

Human subjects: Consent was obtained from all participants in this study. The Institutional Ethics Committee of NIMS University Rajasthan, Jaipur, approved the study (Approval No: NIMSUR/IEC/2022/353) on 16/09/2022. **Animal subjects:** This study did not involve animal participants or tissue. **Conflicts of interest:** The authors declare no financial or non-financial conflicts of interest related to this work. **Funding:** No external funding was received.

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