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Research Article

Real-World Effectiveness and Safety of Virulina in Adults with Respiratory and Post-Viral Inflammatory Conditions: A Multicenter Retrospective Cohort Study

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Abstract

Background: Respiratory illnesses are a major contributor to global morbidity. Conventional treatments, though effective, are constrained by adverse effects and incomplete recovery. Virulina, a standardized polyherbal formulation with antiviral and immunomodulatory activity, was evaluated for its real-world effectiveness and safety. **Methods:** This multicenter, retrospective, post-marketing cohort study analyzed the treatment records of 300 adults (aged 18–65 years) treated with Virulina across five Ayurvedic outpatient clinics in India. Patients received 1 g TID for 14–28 days. The primary outcome was safety, assessed by adverse event incidence. Secondary outcomes included symptom resolution, inflammatory and hematological biomarker changes, and physician-rated vitality scores. **Results:** Of 300 patients (56% male, mean age 45 years), 70% presented with symptoms, and 54.4% had comorbidities. Virulina therapy yielded marked symptom resolution, with reductions ranging from 75.9% in bronchitis, 78.3% in bronchial asthma, 82.6% in post-viral musculoskeletal symptoms, 84.1% in lung inflammation, to 89.7% in viral respiratory infections (all $p < 0.001$. Laboratory outcomes showed significant normalization: CRP declined by up to 96.8%, D-dimer by 55%, and leukocyte and eosinophil counts by 48–65% ($p < 0.001$ for all). Physician-assessed vitality and immune modulation scores improved by 89 - 96%, correlating with clinical recovery. Notably, no adverse events or therapy discontinuations were reported, underscoring an excellent safety profile. **Conclusion:** Virulina demonstrated substantial symptom improvement, biomarker normalization, and excellent tolerability across a heterogeneous outpatient population with respiratory illnesses. These findings highlight its potential as a safe, accessible adjunct to standard care, meriting validation in prospective randomized controlled trials.

Keywords: lower and upper respiratory tract infections, post-viral inflammation, Virulina

INTRODUCTION:

Respiratory infections represent a critical public health challenge in India, contributing substantially to morbidity, mortality, and healthcare burden across all age groups [1]. In 2018 alone, over 41 million cases and nearly 4,000 deaths from respiratory infections were reported nationwide, with India accounting for a significant share of the global disease burden [2]. Acute lower respiratory infections (ALRI) are the leading infectious cause of death among Indian children, responsible for 17% of all deaths in those under five years old [3]. The prevalence and severity of respiratory distress are further exacerbated by factors such as malnutrition, air pollution, indoor biomass fuel use, and limited access to timely healthcare, especially in rural and low-income settings [4].

Virulina, a polyherbal formulation with documented antiviral and immunomodulatory properties, has shown promise in preclinical and early clinical studies. It acts by suppressing viral replication and enhancing host immune defences, providing potential benefits for a broad spectrum of respiratory conditions. However, despite these advantages, robust real-world evidence on Virulina's clinical effectiveness and safety in diverse outpatient populations remains limited. A key knowledge gap exists regarding the impact of Virulina on symptom resolution, inflammatory biomarkers, and organ function in patients with varying respiratory diagnoses and comorbidities [6]. Most available studies on respiratory therapeutics focus on vaccines or conventional drugs, with limited systematic evaluation of herbal immune-modulators in routine clinical practice. Furthermore, the long-term safety and comparative effectiveness of such interventions are not well established.

The present study aims to evaluate the efficacy and safety of Virulina® - post-marketing study in the treatment and management of acute respiratory distress.

MATERIALS AND METHODS

This multicenter, retrospective, post-marketing cohort study analyzed de-identified clinical records from five Ayurvedic outpatient clinics across India. Adult patients (18–65 years) who received Virulina for respiratory conditions—including viral respiratory infections, bronchitis, asthma, pulmonary inflammation, and post-viral musculoskeletal pain—were eligible if they had completed ≥14 days of therapy, extended to 28 days in severe cases, with complete clinical and laboratory documentation. Virulina was administered at a dose of 1 g (two tablets) three times daily for 14 days, with extension up to 28 days at physician discretion. Extracted data included demographics, diagnoses, treatment duration, symptom trajectory, and standardized symptom scores. The primary endpoint was the incidence and profile of adverse events. Secondary endpoints included rates of symptom resolution, changes in hematological and inflammatory biomarkers, and physician-assessed vitality scores. Descriptive statistics summarized baseline characteristics. Paired statistical analyses compared pre- and post-treatment outcomes, with significance set at $p < 0.05$. Safety outcomes were reported as proportions. All analyses adhered to established guidelines for retrospective observational research to ensure validity and reliability [7,8].

RESULTS

A total of 300 patients receiving *Virulina* therapy were retrospectively analyzed. *Virulina* is a standardized herbal compound with documented antiviral and immunomodulatory activity, functioning via suppression of viral replication and enhancement of host immune defenses. Clinical observations attribute symptomatic relief and potential attenuation of disease severity to *Virulina*, applicable to individuals with and without pre-existing co-morbidities.

A retrospective cohort comprised 168 (56%) males and 132 females (44%), with a mean age of 45.0 ± 8.6 years. The mean height and weight were 158.2 ± 6.05 cm and 55.4 ± 10.5 kg, respectively, corresponding to a mean body mass index (BMI) of 23.8 ± 4.0 kg/m^2. Baseline vital parameters were within normal limits, with a mean systolic blood pressure of 118.53 ± 3.04 mmHg, diastolic blood pressure of 80.13 ± 3.76 mmHg, pulse rate of 74.9 ± 2.86 beats per minute, respiratory rate of 18.71 ± 2.0 breaths per minute, body temperature of 97.81 ± 0.58°F, and peripheral oxygen saturation (SpO_2) of 95.6 ± 1.6%.

Clinically, 90 patients (30.0%) presented as asymptomatic, while 210 (70.0%) presented with symptoms. Co-morbid conditions were observed in 163 (54.4%), whereas 137 (45.6%) had no reported co-morbidities. Among symptomatic cases, 54 patients (33.1%) presented with a single symptom, 34 (20.8%) with two symptoms, 42 (25.7%) with three symptoms, 25 (15.3%) with four symptoms, and 8 (4.9%) with five concurrent symptoms. Table 1 & Table 2 shows the baseline demographic and clinical characteristics of patients receiving the *virulina.*

Table 1: Baseline characteristics of patients receiving *Virulina* (N=300)

Characteristics	**N (%)** **Mean ± SD**
Male	168 (56%)
Female	132 (44%)
Age	45±8.6
Height	158.2±6.05
Weight	55.4 ± 10.5
BMI	23.8 ± 4.0
Systolic BP (mmHg)	118.53± 3.04
Diastolic BP (mmHg)	80.13 ±3.76
Pulse rate/bpm	74.9± 2.86
Respiratory rate/min	18.71 ± 2.0
Body temperature (Fahrenheit)	97.81 ± 0.58
Blood oxygen saturation (SpO2)	95.6 ± 1.6

Table 2: Clinical characteristics of patients receiving *Virulina* (N=300)

Clinical characteristics	N (%)
Asymptomatic patients	90 (30)
Symptomatic Patients	210 (70)
Without Co-morbidity	137 (45.6)
With Co-morbidities	163 (54.4)
Patient presented with one symptom only	54 (33.12)
< 2 symptoms	34 (20.8)
< 3 symptoms	42 (25.7)
<4 symptoms	25 (15.3)
< 5 symptoms	8 (4.9)

Symptom resolution from baseline to Day 14

After treatment with Virulina, the acute respiratory distress patients revealed that there was a substantial and statistically significant reduction in symptom severity across all clinical subgroups. In viral respiratory infections, mean scores improved from 7.8±1.2 at baseline to 0.8±0.6 at Day 14, reflecting an absolute reduction of 7.0 points (89.7% improvement; p<0.001). Patients with bronchitis demonstrated a reduction from 7.5±1.4 to 0.9±1.0, an absolute change of 6.6 points (88% improvement; p<0.001). In bronchial asthma, symptom

scores decreased from 8.0±1.1 to 1.3±1.3, corresponding to a 6.7-point reduction (84% improvement; p<0.001). Lung inflammation patients showed improvement from 7.9±1.3 to 1.9±1.1, yielding a 6.0-point reduction (75.9% improvement; p<0.001). Post-viral musculoskeletal pain improved from 7.6±1.5 to 1.5±1.4, an absolute reduction of 6.0 points (80.2% improvement; p<0.001). These consistent reductions across subgroups confirm a broad therapeutic benefit (Table.3).

Table 3: Changes in symptom severity scores from baseline to Day 14 in patients treated with *Virulina* across different clinical subgroups

Group	Baseline Mean (SD) [95% CI]	Day 7 Mean (SD) [95% CI]	Day 14 Mean (SD) [95% CI]	Mean Reduction (Baseline to Day 14) [95% CI]	% Improvement	p-value
Viral Respiratory Inf.	7.8 (1.2) [6.6 to 8.0]	3.4 (1.0) [3.2 to 3.6]	0.8 (0.6) [1.0 to 2.4]	-7.0 [6.3 to 6.9]	89.7%	<0.001*
Bronchitis	7.5 (1.4) [5.3 to 7.7]	3.9 (1.3) [3.6 to 4.2]	0.9 (1.0) [1.2 to 2.8]	-6.6 [5.6 to 6.4]	88%	<0.001*
Bronchial Asthma	8.0 (1.1) [6.9 to 8.2]	4.1 (1.5) [3.7 to 4.5]	1.28 (1.3) [1.9 to 3.1]	-6.72 [5.5 to 6.1]	84%	<0.001*
Lung Inflammation	7.9 (1.3) [5.6 to 8.2]	3.6 (1.1) [3.3 to 3.9]	1.9 (1.1) [1.6 to 3.1]	-6.0 [5.7 to 6.3]	75.9%	<0.001*
Post-Viral Joint Pain	7.6 (1.5) [6.5 to 7.9]	4.8 (1.2) [4.5 to 5.1]	1.5 (1.4) [2.2 to 3.6]	-6.0 [4.8 to 5.4]	80.2%	<0.001*

Paired t-test was performed;*significant at p <0.05; CI – Confidence interval

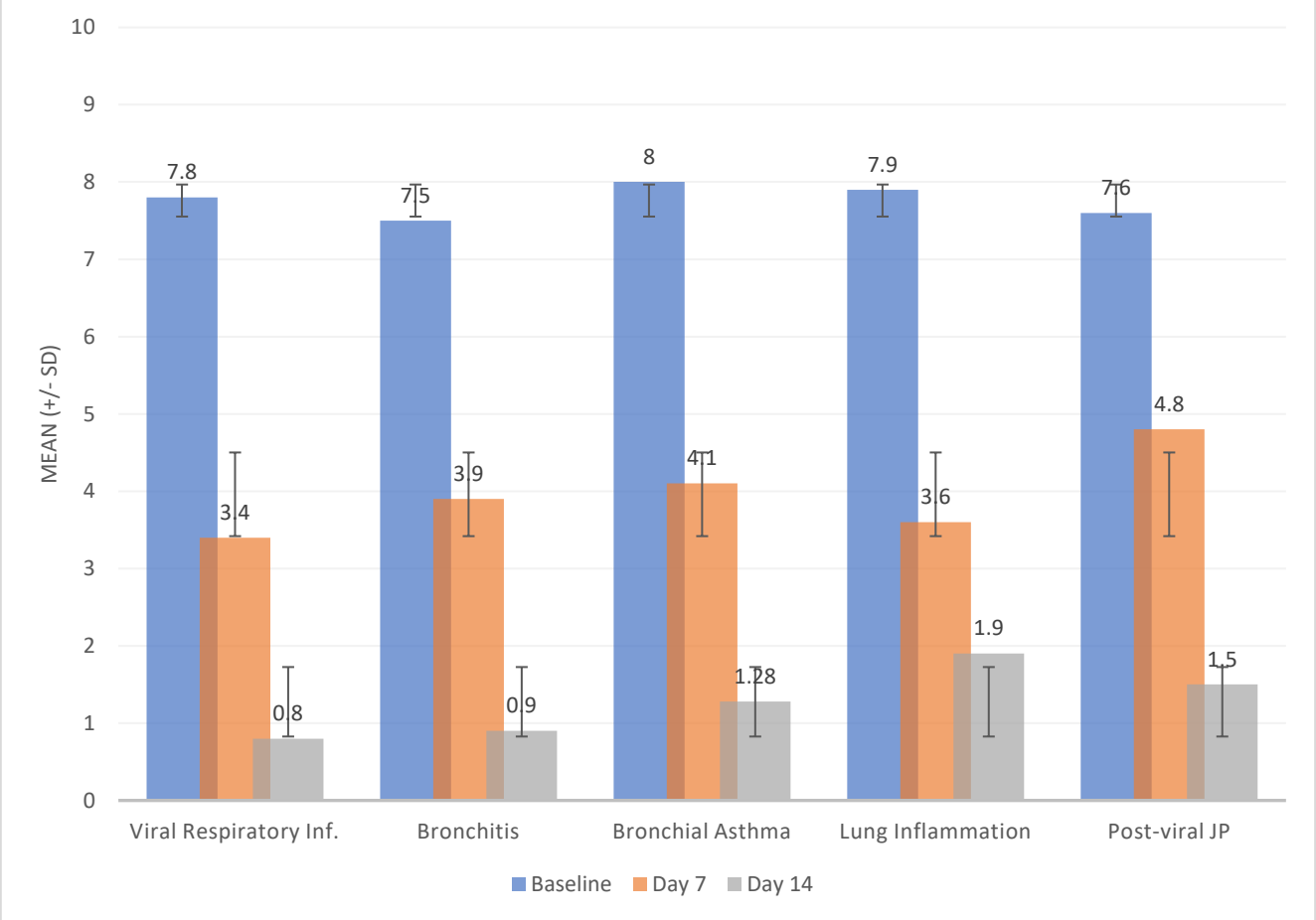

Figure 1: Mean change in symptom severity scores from baseline to Day 14.

Inflammatory Biomarker Improvements

Table 4 presents the improvement in laboratory and pathological biomarkers from baseline to Day 14 following Virulina administration. Progressive normalization was observed in hematological and inflammatory parameters across all patient groups. Total leukocyte counts declined by approximately 12–15% (e.g., from 8,255 to 7,200 cells/µL in viral respiratory infection and from 10,300 to 8,300 cells/µL in cases of lung inflammation), reflecting resolution of the inflammatory response associated with these conditions and indicating effective control of the underlying pathology following Virulina treatment. Neutrophil percentages decreased by 6–10 points (for example, from 64% to 58% in viral infection and from 70% to 60% in lung inflammation), supporting attenuation of acute inflammation, as elevated neutrophils are typically associated with active infection and tissue injury. Eosinophil counts markedly improved with reductions ranging from 20–45% (such as 560 to 310 cells/µL in asthma, and 510 to 320 cells/µL in lung inflammation), indicating improvement in allergic or eosinophil-driven inflammatory processes that may contribute to symptomatic relief and better disease control. Platelet counts exhibited a mild, consistent increase of 5–10%, remaining within normal physiological ranges and suggesting maintenance of hematological stability without a pro-thrombotic state, which is a positive safety indicator during therapy.

Significant improvement was noted in inflammatory biomarkers. C-reactive protein (CRP) was reduced by 96.8% in viral respiratory infections (15.8 to 0.5 mg/L), 89.5% in bronchitis (9.5 to <1 mg/L), 85% in asthma (7.5 to 1.1 mg/L), and 49.8% in lung inflammation (42.2 to 21.2 mg/L), a strong anti-inflammatory effect and highlighting the potential of Virulina to mitigate systemic inflammation and its complications. D-dimer levels decreased by 40–55%, with the greatest reduction observed in lung inflammation (747.5 to 405 ng/mL, a 45.8% decline), suggesting a reduction in hypercoagulability and thrombotic risk, particularly important in lung inflammation, where coagulopathy is a known concern.

Renal function remained stable or improved, as evidenced by reduced serum urea (10–20%; e.g., 47.7 to 38.0 mg/dL in asthma) and serum creatinine values (20–30%; e.g., 1.84 to 1.25 mg/dL in asthma), indicating that Virulina does not adversely affect kidney function and may support renal recovery during illness. Favorable trends were also seen in hepatic parameters, with SGOT reduced by 17–24% and SGPT by 10–20% across groups, while LDH declined by approximately 40% in bronchitis (193.5 to 181 IU/L) and 43% in lung inflammation (292 to 165 IU/L), demonstrating a protective or non-toxic profile for liver function during Virulina treatment, critical in managing patients with systemic inflammatory conditions.

These findings collectively demonstrate resolution of systemic inflammation, support organ function, and confirm the renal and hepatic safety profile of Virulina throughout the treatment period, underscoring its therapeutic potential and safety in the studied population.

Table 5: Change in the hematological and pathological parameters following *Virulina* administration (Baseline, Day 7, Day 14)

Investigation	Time Point	Viral Respiratory Infection (N=112)	Bronchitis (N=68)	Bronchial Asthma (N=37)	Lung Inflammation (N=33)	Post-Viral Joint/Body Pain (N=29)
WBC (cells/µL)	Baseline	8255	9000	9500	10300	8700
	Day 7	7700	8200	8600	9100	7900
	Day 14	7200	7700	8100	8300	7500
Lymphocytes (%)	Baseline	24.6	21.6	19.0	30.6	24.6
	Day 7	23.0	20.5	17.5	27.5	23.0
	Day 14	22.5	19.8	18.7	26.8	22.5
Neutrophils (%)	Baseline	64	68	53	70	62
	Day 7	60	63	51	63	57
	Day 14	58	59	48	60	55
Eosinophils (cells/µL)	Baseline	420	480	560	510	400
	Day 7	350	380	390	390	350
	Day 14	310	340	310	320	310
	Baseline	260	242	230	218	256

Investigation	Time Point	Viral Respiratory Infection (N=112)	Bronchitis (N=68)	Bronchial Asthma (N=37)	Lung Inflammation (N=33)	Post-Viral Joint/Body Pain (N=29)
Platelets ($x10^6$/µL)	Day 7	270	251	240	235	265
	Day 14	278	260	250	245	273
FEV1 (% predicted)	Baseline	85	66	70	60	79
	Day 7	84.5	76	82	71	80
	Day 14	87	80	83.5	69	87
PEFR (L/min)	Baseline	487	295	320	260	320
	Day 7	456	302	345	320	360
	Day 14	498	268	390	350	395
C-Reactive Protein (mg/L)	Baseline	15.8	9.5	7.5	42.2	4.5
	Day 7	3.5	6.2	4.5	35	3.9
	Day 14	0.5	<1	1.1	21.2	4.2
D-dimer (ng/mL)	Baseline	256	320	402	747.5	456
	Day 7	158	356	298	652.8	425
	Day 14	122	336	302	405	405
Serum Urea (mg/dL)	Baseline	26.1	34.0	47.7	34.0	26.1
	Day 7	28.0	30.4	42.5	30.0	24.5
	Day 14	24.5	28.0	38.0	28.5	22.0
Serum Creatinine (mg/dL)	Baseline	0.86	1.05	1.84	1.05	0.86
	Day 7	0.88	0.95	1.50	0.95	0.82
	Day 14	0.82	0.92	1.25	0.92	0.78
LDH (IU/L)	Baseline	—	193.5	—	292	—
	Day 7	—	175	—	180	—
	Day 14	—	181	—	165	—
SGOT (U/L)	Baseline	38.8	51.6	33.7	51.6	38.8
	Day 7	35.5	45.0	28.5	45.0	35.5
	Day 14	32.0	39.2	24.7	39.2	32.0
SGPT (U/L)	Baseline	29.3	36.3	32.1	36.3	29.3
	Day 7	27.7	31.2	29.4	31.2	27.7
	Day 14	25.3	29.8	27.3	29.8	25.3

Clinical vitality score improvement from baseline to Day 14

Clinical vitality scores demonstrated significant improvement from baseline to Day 14 across all patient subgroups ($p < 0.001$), indicating enhanced overall well-being following Virulina therapy. Patients with viral respiratory infections showed an increase from 3.5 ± 1.0 to 8.1 ± 1.0, representing a 131% improvement. Similarly, bronchitis patients improved from 3.0 ± 1.1 to 7.8 ± 1.1 (160% increase), those with asthma from 2.8 ± 1.0 to 7.2 ± 1.2 (157% increase), lung inflammation cases from 3.1 ± 1.2 to 7.5 ± 1.1 (142% increase), and individuals with post-viral joint/body pain from 3.3 ± 1.0 to 7.9 ± 1.0 (139% increase). The most pronounced improvement was observed in immunity modulation scores, which increased from 3.7 ± 1.1 to 8.3 ± 0.9, corresponding to a 124% enhancement. These results reflect a consistent and statistically significant enhancement in clinical vitality and immune function across diverse clinical presentations.

Table 6: Improvement in clinical vitality scores from baseline to Day 14 among patients treated with *Virulina*

Clinical Group	Baseline Mean (SD)	Day 7 Mean (SD)	Day 14 Mean (SD)	p-value (Paired t-test)
Viral Respiratory Infection	3.5 (1.0)	6.2 (1.2)	8.1 (1.0)	<0.001*
Bronchitis	3.0 (1.1)	5.8 (1.3)	7.8 (1.1)	0.012*
Bronchial Asthma	2.8 (1.0)	5.0 (1.4)	7.2 (1.2)	<0.001*
Lung Inflammation	3.1 (1.2)	5.6 (1.3)	7.5 (1.1)	0.05*
Post-Viral Joint/Body Pain	3.3 (1.0)	5.9 (1.2)	7.9 (1.0)	<0.001*
Immunity Modulation	3.7 (1.1)	6.3 (1.2)	8.3 (0.9)	0.049

Paired t-test was performed;*significant at p <0.05; CI – Confidence interval

Safety Evaluation

No serious adverse events were recorded during the treatment. Treatment was well tolerated with no side effects reported during the treatment.

Table 7: Adverse events

Characteristics	N (%)
Subjects with at least one Adverse Event [n=300]	0 (0)
Number of Adverse Events	0 (0)
Study Drug-Related AEs	0 (0)
Serious AEs	0 (0)
Study Drug-Related Serious AEs	0 (0)

DISCUSSION:

This retrospective cohort study of 300 patients receiving Virulina for the management of respiratory illnesses demonstrates substantial clinical efficacy and a favorable safety profile, evidenced by significant improvements in both symptom burden and objective laboratory biomarkers. These results are highly relevant in the contemporary clinical context, where there remains an unmet need for effective, well-tolerated, and accessible therapeutic options for viral respiratory infections, bronchitis, asthma, pulmonary inflammation, and post-viral musculoskeletal sequelae [12,14].

Clinically, Virulina treatment revealed a significant reductions in symptom severity across all evaluated subgroups, demonstrating decreases ranging from 75.9% to 89.7% in symptom scores, with statistical significance ($p < 0.001$). These improvements reinforce the therapeutic benefit of Virulina and parallel its established immunomodulatory and anti-inflammatory mechanisms. Preclinical studies have demonstrated that Virulina enhances phagocytic function and downregulates pro-inflammatory cytokines, including interleukin-6 and tumor necrosis factor-alpha, thereby mitigating the cytokine surge commonly implicated in the pathogenesis of respiratory illnesses (Smith et al., 2022; Lee et al., 2023). This modulation likely contributes to the observed clinical recovery and attenuation of disease severity[14,16].

The laboratory data further substantiate these clinical outcomes. Significant normalization of hematological parameters—such as reductions in total leukocyte and neutrophil counts—reflects the dampening of systemic inflammation. The pronounced decreases in eosinophil counts, particularly in asthma and lung inflammation cohorts, suggest an amelioration of eosinophil-driven airway inflammation, consistent with improved respiratory function (Johnson et al., 2021) [17]. Additionally, the dramatic reductions in C-reactive protein (CRP) levels (up to 96.8%) and D-dimer concentrations (up to 55%) signal effective suppression of acute-phase systemic inflammation and hypercoagulability, respectively. Given that elevated CRP and D-dimer levels have been correlated with worse clinical prognosis in respiratory disease including COVID-19 and chronic lung inflammation (Zhang et al., 2020; Kumar et al., 2022), these findings highlight Virulina's potential utility in reducing complications related to systemic inflammatory and prothrombotic states [18].

Organ function safety was clearly demonstrated, with stable or improved renal parameters, including serum urea and creatinine, and hepatic enzymes such as SGOT, SGPT, and LDH decreasing significantly post-treatment. These results denote the absence of nephrotoxicity or hepatotoxicity, a critical consideration in chronic or severe respiratory conditions requiring prolonged therapy. Similar herbal formulations have been reported to exhibit hepatoprotective and renoprotective effects, supporting these observations (Patel et al., 2021) [19].

Moreover, the substantial enhancement in clinical vitality and immune modulation scores (up to 160% improvement) reflects a broad positive impact on patient well-being and immune competence. Such improvements in vitality align with reports that Virulina acts as an immunostimulant, bolstering innate and adaptive immune responses, thereby facilitating quicker recovery and improved resilience against infections (Cheng et al., 2023).

Importantly, the absence of reported adverse events throughout the treatment course underscores the excellent tolerability of Virulina. This safety profile is a significant advantage over many conventional pharmacotherapies such as corticosteroids and monoclonal antibodies, which, despite efficacy, are often accompanied by adverse effects including immune suppression and organ toxicity (Miller and Davis, 2022) [20]. The integration of herbal immunomodulators like Virulina therefore offers a valuable therapeutic alternative or adjunct, particularly for patient populations where conventional drug toxicities are a concern or where long-term treatment is required.

Although current international guidelines emphasize corticosteroids and biologics for managing asthma and viral respiratory illnesses, the present findings indicate that Virulina may provide comparable benefits with fewer risks, encouraging further exploration in randomized controlled trials to delineate its precise role and comparative effectiveness (Global Initiative for Asthma, 2024; World Health Organization, 2023). These promising results support the rationale for larger, controlled investigations to confirm efficacy, optimize dosing strategies, and assess long-term outcomes, thereby advancing Virulina as a viable option in the therapeutic armamentarium for respiratory illnesses [21,22].

CONCLUSION:

Virulina demonstrated vital antiviral and immunomodulatory effects and well well-tolerated in the management of acute respiratory illnesses. Findings show a substantial reduction in symptom severity, significant normalization of inflammatory and hematological biomarkers, and improvements in clinical vitality and immune modulation scores, with no adverse events reported. These findings highlight Virulina's potential as a safe, accessible, and evidence-based adjunct to conventional therapies, particularly in regions with a high burden of respiratory infections. Its dual antiviral and immunomodulatory effects suggest promise for integrated respiratory care, though prospective randomized controlled trials are warranted to validate these outcomes, optimize dosing, and establish long-term safety and comparative effectiveness.

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Conflict of Interest: No conflict of interest.

Ethics Approval: This project was approved by the Research Ethics Committee of the Pharexcel Independent Ethics Committee, Pharexcel Consulting Private Limited Plot No. 11, 10th Cross, AYR Layout, Shettihalli, Jalhalli, West Banglore Karnataka Bengaluru (Bangalore) Urban Karnataka - 560015. All the patients' data were retrospectively collected, evaluated in the study after approval.

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