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Research article

Novel phyto-therapeutic and immune modulation interventions in managing acute respiratory distress syndrome: a case series

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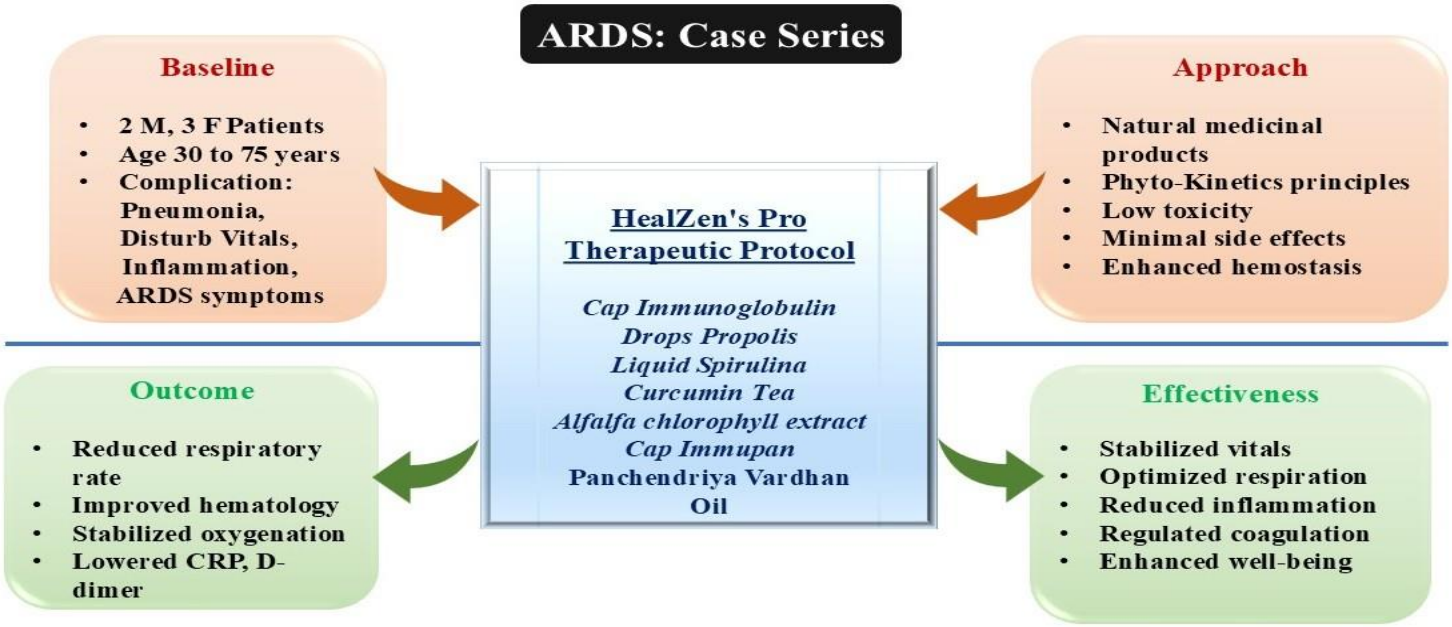
ABSTRACT

Acute Respiratory Distress Syndrome (ARDS) is a severe and life-threatening condition marked by acute lung injury, poor oxygenation, and significant inflammatory responses. Despite advancements in supportive care, including mechanical ventilation and pharmacotherapy, ARDS remains challenging to treat, with high mortality rates globally. This case series discusses a novel approach to ARDS management using Healzen's "Pro Therapeutic Protocol," which leverages natural medicinal products rooted in Phyto-Kinetics principles. These products include immunoglobulins from cow colostrum, Ayurvedic formulations, and potent antioxidants like spirulina and curcumin, designed to enhance immune function, reduce inflammation, and support overall recovery. Clinical case studies demonstrate the protocol's effectiveness, showing marked improvements in vital signs, respiratory function, inflammatory markers, and clotting activity across five multiple patients. The outcomes suggest that these natural interventions can serve as valuable adjuncts in ARDS treatment, offering lower toxicity and fewer side effects compared to conventional therapies.



Keywords: HealZen's Pro Therapeutic Protocol, Acute Respiratory Distress Syndrome, Phyto-kinetics, Immunomodulation.

INTRODUCTION

Acute Respiratory Distress Syndrome (ARDS) is a critical and potentially fatal condition characterized by a sudden, widespread inflammatory injury to the lungs, commonly affecting critically ill patients. It manifests with poor oxygenation, pulmonary infiltrates, and an acute onset. On a microscopic level, ARDS is marked by capillary endothelial injury and diffuse alveolar damage [1].

More than 3 million people are diagnosed with ARDS each year. The incidence among critically ill patients in ICUs is 10% [2]. The mortality rate remains high, ranging from 35 % to 50%, depending on the severity and the underlying health conditions of the patients [3]. The prevalence of ARDS in India is significant, especially among critically ill patients in ICUs. In India, pneumonia constitutes 30% of ARDS cases, while gastrointestinal diseases account for 25% and polytrauma for 12%. These factors represent the primary causes contributing to the incidence of ARDS within the country [4].

The existing treatment approaches for ARDS focus on improving oxygen levels and managing underlying causes through oxygen therapy (nasal tubes, masks, or tracheal tubes), breathing support like noninvasive ventilation or mechanical ventilation, and medications such as acid reducers, antibiotics, corticosteroids, and inhaled pulmonary vasodilators. Additionally, some investigative therapies, including Vitamin C, beta-agonists, statins, mesenchymal stromal cells, granulocyte-macrophage colony-stimulating factors, and blood thinners are used to alleviate symptoms and prevent complications. Additional treatments include feeding tubes for nutrition, extracorporeal membrane oxygenation (ECMO) in severe cases, fluid management, and physical therapy to aid recovery and prevent muscle weakness [5-7].

Despite these significant progress in understanding the underlying causes of ARDS, developing specific therapies to effectively address lung injury and inflammation remains a challenge [7]. Currently, optimizing supportive therapies such as spontaneous breathing and adjusting ventilator settings according to the condition of the lungs are key challenges in the treatment of ARDS. Issues such as managing mechanical ventilation asynchronies, evaluating the impact of mechanical power, and comparing higher positive end-expiratory pressure (PEEP) with prone positioning are under investigation. The complexity of ARDS pathogenesis, involving multiple injury mechanisms, likely explains why no single pharmacologic treatment has proven definitively beneficial. Interventions targeting individual mediators may be insufficient due to the multifaceted nature of the disease [2, 6, 7].

Alternatively, some recent research has investigated several natural products using experimental models, demonstrating their ability to inhibit various inflammatory pathways linked to acute lung injury and ARDS on a molecular level [8-13]. These agents are noted for their pleiotropic effects, often activating antioxidant pathways via nuclear factor erythroid-related factor 2 (Nrf2), which enables them to target multiple pathways simultaneously. Many of these products are commonly used to treat inflammatory conditions in the Asian subcontinent and have shown promising safety profiles in clinical settings [7].

MATERIALS AND METHODS

Treatment Plan and Goals

In response to ARDS, Halen has created natural medicinal products to address the condition. By understanding the virus-host immune interaction and the role of lung inflammation, Healzen's "Pro Therapeutic Protocol for ARDS" uses advanced Phyto-Kinetics to enhance cellular resilience. This treatment regimen was consistently applied to all patients as described below.

The approach included innovative products such as

Cap Immunoglobulin (31.5% IgG Cow Colostrum)

Rich in about 400 proteins, including immunoglobulin's (IgG), lactoferrin, cytokines, lysozyme, and growth factors. These components enhance immune defense and overall health by detecting and responding to pathogens [8].

Drops Propolis

Propolis is a potent immunomodulatory and antioxidant with over 300 active compounds, including flavonoids like quercetin and compounds such as pinocembrin and naringenin. Immushield uses these properties to block viral polymerase activity and nucleic acid synthesis, making it a strong antiviral agent [9].

Liquid Spirulina

Spirulina is a nutrient-rich blue-green microalga known for its high protein content and bioactive compounds. It has anti-inflammatory and antiviral properties, boosts immune function, and may enhance the body's defense against viral infections, providing immune support and viral protection [10].

Curcumin Tea

Curcumin, a phyto-derivative with healing properties, supports immune function and reduces liver toxicity. Its strong immunomodulatory and anti-inflammatory effects, coupled with high bioavailability, help suppress inflammatory molecules, alleviate symptoms, and reduce viral replication, effectively lowering viral load [11].

Alfalfa chlorophyll extract

It is a potent health molecule with anti-inflammatory, antiviral, and antioxidant benefits. Chlorophyllin reduces inflammation by inhibiting lipopolysaccharide-induced TNF-α and neutralizing oxidants, while L-canavanine, a non-protein amino acid found in alfalfa leaves and roots, exhibits antiviral properties [12, 14, and 15].

Cap Immupan, an immunomodulatory formulation containing essential nutrients, and Panchendriya Vardhan Oil, a nasal

preparation with 23 Ayurvedic ingredients for enhancing sensory and cranial nerve function, were both utilized in the patients' treatment regimen.

Additionally, as suggested by clinicians Dolo 650 (paracetamol) may be used to manage fever and mild pain in ARDS patients, improving comfort but not treating ARDS directly. It should be used under medical supervision, as ARDS management focuses on addressing underlying causes and providing supportive care like oxygen therapy and mechanical ventilation.

The Pro Therapeutic Protocol enhances immune function and overall well-being by targeting viral infections through virus replication inhibition, viral particle clearance, and tissue repair. It focuses on strengthening of natural enzymes, the protocol promotes cellular detoxification, innate immunity, and apoptosis, allowing cells to eliminate the immune response for effective healing and long-term adaptive defense. Utilizing a potent combination waste and prevent pathogen infiltration, thus ensuring a smooth flow of life energy and promoting health.

Post-ARDS Patient Care and Follow-Up Directions

Post-ARDS care emphasizes recovery and rehabilitation, using a multidisciplinary approach to address physical, emotional, and cognitive health. Please note, this follow-up protocol is standard for all cases and uniformly applied to all patients.

An overview of post-ARDS care and the potential role of Healzen's Post care protocol

Respiratory Rehabilitation

Breathing exercises

Techniques like diaphragmatic breathing and incentive spirometry to improve lung function.

Physical therapy

Gradual mobilization to restore strength and endurance.

Functional Nutritional Support

Balanced diet

High in protein and calories to promote healing and maintain energy levels.

Hydration

Ensuring adequate fluid intake to support recovery.

Psychological Support

Counselling

Addressing anxiety, depression, or Post-Traumatic Stress Disorder PTSD, which can occur after a severe illness.

Support groups

Connecting with others who have experienced ARDS for emotional support.

Monitoring and Follow-Up

Regular check-ups

To monitor lung function and overall health.

Medications

Chlorophyll 10ml (Early Morning empty stomach)

This approach ensures a comprehensive recovery for ARDS survivors by integrating physical, nutritional, psychological, and medical support tailored to their needs. Follow-up emphasized continuous monitoring to sustain the benefits achieved with the Pro Therapeutic Protocol and supplements like liquid Chlorophyll, Immunoglobulins, and multivitamins. Adjustments were based on patient responses, eliminating the need for broad-spectrum antivirals. Regular appointments were scheduled to assess health indicators, with future plans focused on refining immune therapies, improving respiratory function, and managing long-term effects in line with post-ARDS care guidelines.

Case Presentation

Case 1

In June 2021, a 54-year-old male patient 50 kg and 155 cm tested positive for Covid-19 and developed ARDS. He presented with fever, weakness, anorexia, cold, and cough. Initial diagnostics revealed a respiratory rate of 22 bpm, a mild fever of 99.4°F, an elevated WBC count of 19,550 /cu-mm, and D-dimer high as 389.2 ng/mL. His pre-existing conditions complicated treatment, underscoring the need for detailed medical records.

Case 2

A 30-year-old female with COVID-19 and ARDS presented with persistent cough, cold, fever, anorexia, and weakness. Prior diagnostics showed a respiratory rate of 22 bpm, a temperature of 100°F, a low WBC count of 2,800 cells/cu mm, a platelet count of 110,000/cu mm the lower end of normal, increased CRP levels of 43.99 mg/dL and a D-dimer level of 513 ng/ml, indicating potential clotting activity or other issues needing further investigation.

Case 3

A 75-year-old female with symptoms of ARDS, including cough, cold, fever, anorexia, and weakness, presented for evaluation. Current lab results showed a CRP of 6 mg/dl and a D-dimer of 389.2 ng/ml, which aided in assessing her condition and guiding further treatment.

Case 4

A 40-year-old, 44 kg female with ARDS presented with loss of taste, persistent cough, dyspnea, anorexia, and weakness. Diagnostic results revealed anaemia with Hb level of 10.3 g/dl, an elevated WBC count of 11,200 cells/mcL suggesting inflammation or infection, and an increased platelet count of 427,000 cells/mcL indicating thrombocytosis. Elevated inflammatory markers included CRP at 3.04 mg/dl and D-dimer at 236.65 ng/ml, signaling ongoing inflammation. Further investigation was needed to clarify these findings.

Case 5

A 24-year-old, 73 kg male with ARDS from COVID pneumonia presented with loss of taste, cough, dyspnea, anorexia, and general weakness. His abnormal values included elevated BP at 140/90 mmHg, indicating hypertension. The heart rate was high at 100 bpm, suggesting tachycardia. The platelet count was low at 121,000 cells/cu mm, indicating thrombocytopenia. The CRP level was significantly

elevated at 29 mg/dL, signaling substantial inflammation. Additionally, the D-dimer level was high at 810 ng/mL, suggesting ongoing clotting activity. This case underscored the need for timely intervention and comprehensive management of COVID-19-related respiratory complications.

As previously noted, all patients were treated according to Healzen's Pro Therapeutic Protocol, and similar post-ARDS care was provided to each patient.

Declaration of Patient Consent

The authors affirm that the data published in this manuscript is in accordance with the informed consent obtained from the participants.

RESULTS

Table 1 summarizes the pre-and post-treatment clinical findings and results for the five patients included in this study.

Table 1: Pre-treatment clinical findings and post-treatment results

	Parameters	Blood Pressure (mmHg)	Heart Rate (bpm)	Respiratory rate (Breath/minute)	Hemoglobin (Hb) g/dl	RBC count (/cu-mm)	WBC count (/cu-mm)	Platelet count (/cu-mm)	C-Reactive Protein (CRP) (mg/dl)	D-DIMER (ng/ml)
Case 1	Pre-Treatment	110/70	96	22	15.3	5.07	19550	208000	11	389.2
	Post -Treatment	120/80	94	18	12.3	4.12	6030	294000	Negative 1.2	180.5
Case 2	Pre-Treatment	120/80	88	22	12	6.19	2800	110000	43.99	513
	Post -Treatment	120/80	84	20	12.8	5.16	9160	268000	Negative 1.8	240
Case 3	Pre-Treatment	130/80	86	20	13	4.23	5300	246000	6	389.2
	Post -Treatment	130/80	84	22	11.4	3.97	8020	254000	Negative 2.13	180.5
Case 4	Pre-Treatment	130/80	86	20	10.3	4.73	11200	427000	3.04	236.65
	Post -Treatment	120/70	76	18	10.7	4.75	9600	393000	2.3	120.4
Case 5	Pre-Treatment	140/90	100	20	13.9	5.4	8600	121000	29	810
	Post -Treatment	130/80	86	16	14.1	5.43	10500	186000	2.9	512

Case 1

As shown in Table 1, post-therapeutic treatment data reveal several improvements in patient health. The respiratory rate decreased to 18 bpm, suggesting enhanced respiratory function and possibly reduced distress [16]. The WBC count fell to 6,030/cu-mm, indicating a significant reduction in inflammation or infection, which suggests a positive response to the treatment [17]. CRP levels were reduced from 11 mg/dL to negative 1.2 mg/dL, indicating the resolution of systemic inflammation and underscoring the treatment's effectiveness in managing inflammatory processes [18]. Additionally, D-dimer levels decreased to 180.5 ng/mL, reflecting diminished abnormal clotting activity and fibrin breakdown, which may signal a decrease in thrombotic events or an improvement in coagulation status [19]. During treatment, the patient maintained stable SpO2 levels, effectively controlled fever, and reduced viral load. Regular post-treatment monitoring, scheduled for 9th June, 2021, aimed to assess the regimen's effectiveness in combating the infection and restoring health.

Case 2

As illustrated in Table 1, significant clinical findings include a decrease in respiratory rate to 20 bpm post-treatment, indicating improved respiratory function [16]. The normalization of the platelet count to 268,000/cu-mm signifies improvements in haematological parameters [20]. The elevated WBC count of 9,160/cu-mm post-treatment may reflect a rebound from the initially low count or an active immune response as the body recovers [17]. Additionally, the substantial reduction in CRP to negative 1.8 mg/dL demonstrates a marked decrease in systemic inflammation, highlighting the effectiveness of the treatment in managing inflammatory processes [18]. The reduction in D-dimer levels to 240 ng/mL post-treatment demonstrates the therapy's effectiveness in addressing hypercoagulability [19]. Clinically, the patient maintained adequate oxygen saturation SpO2, suppressed viral load, and experienced controlled fever. A post-treatment assessment was given onwards from 2nd June, 2021.

Case 3

As shown in Table 1, after treatment, the patient's vital signs remained stable. The slight increase in respiratory rate from 20 to 22 bpm may indicate ongoing respiratory challenges or adaptation. Hemoglobin decreased from 13 g/dL to 11.4 g/dL, though still within normal limits. The elevated WBC count 8020 /cu-mm could be attributed to various causes such as infections or inflammation [21]. The significant reduction in CRP from 6 mg/dL to negative 2.13 mg/dL suggests effective management of systemic inflammation by the plant-based treatment [18]. Additionally, the decrease in D-dimer levels from 389.2 ng/mL to 180.5 ng/mL indicates improved coagulation status and a reduced risk of thrombotic events [19]. Regular post-treatment assessments, was given from 29th May, 2021.

Case 4

From Table 1, the clinical findings demonstrate notable improvements post-treatment. The reduction in respiratory rate from 20 to 18 bpm suggests enhanced respiratory function and less distress [16]. The decrease in WBC count to 9,600/cu-mm indicates a reduction in systemic inflammation or infection, reflecting an improved immune response [17]. The platelet count has returned to a normal level of

393,000/cu-mm**.** Additionally, CRP levels decreased to 2.3 mg/dL, showing effective management of systemic inflammation [18]. The reduction in D-dimer levels to 120.4 ng/mL signifies progress in reducing abnormal clotting activity and enhancing coagulation status [19].

Case 5

Table 1 gives, the clinical findings for the patient reveal several key improvements. The reduction in BP to 130/80 mmHg indicates enhanced cardiovascular health and a positive response to treatment. A decrease in heart rate to 86 bpm suggests better cardiovascular function and reduced cardiac stress. An increase in WBC count to 10,500/cu-mm indicates an active immune response, potentially reflecting the body's reaction to the treatment [17]. The significant reduction in CRP levels to 2.9 mg/dL shows effective management of systemic inflammation [18]. Finally, the decrease in D-dimer levels to 512 ng/mL suggests progress in reducing abnormal clotting activity and improving coagulation status, although levels remain elevated [19].

DISCUSSION

The analysis of the five cases demonstrates the effectiveness of the "Pro Therapeutic Protocol" in managing physiological parameters and inflammatory markers.

Case 1 showed significant reductions in respiratory rate and temperature, along with declines in haemoglobin, RBC, and WBC counts, indicating a positive response and effective inflammation management, as reflected by decreased CRP and D-Dimer levels. Case 2 mirrored this success, with improved haemoglobin, WBC, and platelet counts alongside reduced inflammatory markers, contributing to stable oxygen levels. In Case 3, despite a slight increase in respiratory rate, improved WBC counts and decreased CRP and D-Dimer levels indicated effective inflammation control. Case 4 demonstrated similar trends, with better respiratory rate and reductions in inflammatory markers, alongside favourable changes in haemoglobin and RBC counts. Lastly, Case 5 showed reductions in blood pressure and respiratory rate, and although WBC counts suggested ongoing inflammation, significant decreases in CRP and D-Dimer highlighted effective outcomes. Collectively, these cases underscore the protocol's potential in supporting recovery, managing inflammation, and stabilizing critical health parameters [22- 24].

Inclusively, the diverse positive results across all cases highlight the efficacy of the treatment regimens in improving vital signs, enhancing immune responses, and managing inflammation and coagulation. These outcomes underscore the value of tailored therapeutic approaches and the importance of ongoing monitoring for successful ARDS management and patient recovery.

These findings collectively emphasize the importance of tailored therapeutic approaches and vigilant monitoring in achieving sustained recovery and well-being for patients facing severe health complications.

One limitation observed across the discussed treatment regimens is the variability in patient responses and the presence of persistent challenges such as inflammation and immune system dysregulation [25]. Despite positive outcomes in many cases, the need for continuous monitoring and potential adjustments to treatment plans underscores the complexity of managing severe health conditions effectively.

The associated problems in managing ARDS stem from several factors: its complex and varied causes make it unlikely that targeting a single pathway will provide a cure; critically ill patients with ARDS often experience multiple organ failure, limiting their tolerance for drug side effects; and due to the proteinaceous fluid covering the alveoli in ARDS, drugs struggle to be effectively absorbed and utilized. In contrast, natural herbs and their extracts offer distinct advantages in ARDS treatment, such as lower toxicity, reduced side effects, cost-effectiveness, and promising therapeutic potential. Advancing research through evidence-based clinical trials could unveil valuable pharmacological treatments for ARDS utilizing natural medicine approaches [15]. Future research avenues include exploring novel administration methods, to enhance drug absorption. Additionally, investigating combinatorial approaches simultaneous administration of multiple low-toxicity remedies holds promise. Lastly, there's potential in using natural products for preventive purposes in high-risk patients identified through lung injury prediction scores [7].

These findings collectively suggest favourable treatment response and potential recovery from the underlying condition, warranting continued monitoring and clinical assessment to ensure sustained improvement in health status.

CONCLUSION

In conclusion, the treatment regimens across all cases have demonstrated significant effectiveness in managing ARDS and related complications. Each patient's vital signs and key health indicators, including hemoglobin levels, platelet counts, and inflammatory markers, showed marked improvements, reflecting enhanced immune function and reduced inflammation. The Pro Therapeutic Protocol, along with supplemental treatments such as liquid Chlorophyll, Immunoglobulins, and multivitamins, successfully stabilized vital signs, improved respiratory function, and promoted overall recovery. Continued monitoring and adherence to the treatment plans are essential for sustaining these positive outcomes, ensuring ongoing health improvements, and managing any long-term effects of ARDS and COVID-19.

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Conflicts of interest

The authors declare no potential conflicts of interest in relation to this work.

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Conflict of Interest

The authors declare that there is no conflict of interest with this work.

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