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**Inflammatory Phenotypes Can Be Prospectively Identified At The Bedside In Patients With The Acute Respiratory Distress Syndrome; Results From A Multicenter, Prospective, Observational Cohort Study**

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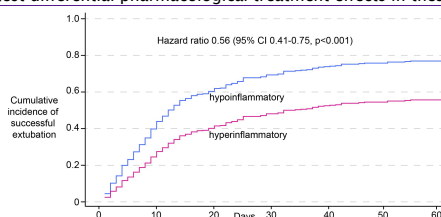
## Abstract:

**RATIONALE:** In patients with acute respiratory distress syndrome (ARDS), the hyperinflammatory and hypoinflammatory phenotypes have been reported to have different outcomes and treatment effects in retrospective analyses of completed clinical trials. We tested the hypothesis that real-time identification of inflammatory phenotypes at the bedside with a point-of-care assay and a validated parsimonious classifier model was feasible.

**METHODS:** Patients with ARDS (defined using identical criteria to the 2024 global definition), were recruited in 30 intensive care units in the United Kingdom and Ireland within 72 hours of ARDS onset. Clinical data were collected at baseline. Freshly collected plasma samples were quantitatively analyzed for interleukin-6 (IL-6) and soluble tumour necrosis factor receptor-1 (sTNFR-1) using an Evidence MultiSTAT point-of-care analyzer (Randox Laboratories Ltd). These values were used along with an arterial bicarbonate measurement in the validated parsimonious regression classifier model to calculate the probability of belonging to the hyperinflammatory phenotype, with a cut-off > 0.5 indicating allocation to the hyperinflammatory phenotype. The primary outcome was difference in mortality at 60 days between the hyperinflammatory and hypoinflammatory ARDS phenotypes (NCT04009330).

**RESULTS:** 512 patients were recruited and consented to data usage. For 22 of these patients (4.2%), phenotype allocation was not possible due to assay failure. The prevalence of the hyperinflammatory phenotype was 18% (89/490). Despite the phenotypes having similar age ranges and pulmonary dysfunction as measured by the PaO<sub>2</sub>/FiO<sub>2</sub> ratio and lung injury score, patients with the hyperinflammatory phenotype were more severely ill as measured by APACHE II and SOFA scores. In patients on high-flow nasal oxygen (HFNO) at enrolment, progression to intubation was more frequent in the hyperinflammatory phenotype (7/89 [63.6%] compared to 27/401 [31.0%]). In the hyperinflammatory phenotype, mortality was higher (51.1% vs. 27.9%; 23.2% difference [95% CI 11.9–34.6]; adjusted OR 2.6 [95% CI 1.6–4.4, p<0.001]) and successful extubation was lower (Figure 1).

**CONCLUSION:** Our large multicenter study indicates that real-time classification of ARDS inflammatory phenotypes is feasible in a real-world setting and that the identified phenotypes have distinct clinical characteristics and outcomes. Our findings advance the field by enabling precision medicine clinical trials, such as the PANTHER trial, to test differential pharmacological treatment effects in these phenotypes.



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