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Title: Intensive care unit acquired pneumonia with or without etiologic diagnosis: A comparison of outcomes

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**Body:** Background: The impact of intensive care unit acquired pneumonia (ICU-AP), without etiologic diagnosis, on patient outcomes is largely unknown. Objective: To compare the clinical characteristics, inflammatory response and outcomes between patients with or without microbiologically confirmed ICU-AP. Methods: We prospectively collected 270 patients with ICU-AP. Patients were clustered according to positive or negative microbiologic results. We compared the baseline characteristics and outcomes between groups. Results: ICU-AP without etiologic diagnosis was found in 82 (38%) patients. In comparison with patients with microbiologically confirmed ICU-AP, patients without etiology presented more frequently chronic renal failure (15, 18% vs. 11, 6%, p=0.003), chronic heart diseases (35, 43% vs. 55, 29%, p=0.044), higher hypoxemia (PaO2/FiO2 165±73 vs. 199±79 mmHg, p=0.001) and shorter intensive care unit (ICU) stay before the onset of pneumonia (5 $\pm$ 5 vs. 7 $\pm$ 9 days, p=0.001). The systemic inflammatory response was similar between groups. Despite similar severity at the ICU admission and onset of pneumonia, in patients with microbiologically confirmed ICU-AP there was higher in-hospital (84, 45% vs. 25, 31%, p=0.040), and 90-day mortality (87, 51% vs. 28, 36%, p=0.043). Conclusion: Microbiologically not confirmed ICU-AP develops earlier and it is associated with better outcomes and specific underlying comorbidities that increase the risk of pulmonary edema, ultimately suggesting a potential misdiagnosis. Supported by: EC07/90390, SEPAR 2009, FUCAP, Ciberes (Ciberes is and initiative of Instituto Carlos III), IDIBAPS, Curetis AG.