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Title: Usefulness of Presepsin (Soluble CD14 Subtype) in the Diagnosis of Neonatal Sepsis

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Background: Sepsis is a major cause of morbidity and mortality in neonates. Recently, presepsin (soluble CD14 subtype) has been shown to be beneficial as sepsis marker in adults. Nevertheless, few data are available in neonates.

Objective: To evaluate the diagnostic accuracy of presepsin as a marker of sepsis in the neonatal period.

Design/Methods: All neonates with clinical signs of sepsis admitted to our Unit during a 18-months period were consecutively enrolled. CDC criteria were used to identify neonates with a suspected sepsis. The subjects enrolled in the study were then classified into 3 groups according to Goldstein's and Wynn's definitions: group 1, infection; group 2, sepsis; group 3, septic shock. To measure presepsin, 100 microliters of blood were collected at the following times: at the onset of clinical signs of sepsis (T0), every 12 h for the next 48 h (T1, T2, T3, T4), and at the end of antibiotic therapy (T5). C-reactive protein (CRP) was determined at the same times. Presepsin levels were determined using Pathfast™ System (LSI Medience Corporation, Japan/Mitsubishi Chemical Europe).

Results: We enrolled 110 neonates: 36 in group 1 (mean GA 34.6 wks, mean BW 2403 g), 59 in group 2 (mean GA 31 wks, mean

BW 1615 g) and 15 in group 3 (mean GA 30.2 wks, mean BW 1441 g). Overall, median presepsin value was 1146 pg/ml at T0, higher than the values we previously reported in healthy neonates (PAS Meeting 2015), and decreased over time to 726 pg/ml at T5. Presepsin levels were significantly higher in neonates with sepsis and in those with septic shock than in the others at T0, T1, T2, T3, and T4 ($p < .05$). Additionally, neonates with septic shock had higher levels of presepsin than those with sepsis at all times. At enrollment, median presepsin value was 874 pg/ml, 1277 pg/ml, and 1928 pg/ml in group 1, 2, and 3 respectively. No significant difference was found in CRP values among the 3 groups at enrollment. The area under the ROC curve for presepsin at enrollment was 0.839 (95% CI: 0.79-0.88). Maximum Youden index was at a cut-off value of 865 pg/ml, corresponding to 75% sensitivity and 80% specificity.

Conclusions: According to our results, presepsin appears an accurate biomarker for the diagnosis of neonatal sepsis and it seems to be earlier than CRP in identifying sepsis and septic shock.

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