

Biomarker for early detection of acute kidney injury

Bimetra, the Clinical Research Center of Ghent University, is seeking partners interested in developing and commercializing a novel test for the early diagnosis of acute kidney injury.

Introduction

Sepsis and acute kidney injury (AKI) can account for up to 40% of critically ill patients hospitalized in intensive care units (ICU). Despite extensive research and recent advances in supportive care and diagnostic tools, severe sepsis and septic shock remain associated with high mortality rates (25-70%). In this context, AKI is a frequent and important complication of sepsis in critically ill patients.

Early and specific diagnosis of AKI is important for the prevention and targeted intervention of sepsis-induced AKI. Recently, several promising biomarkers for AKI have been identified (NGAL, IL-18, NHE3, KIM-1, CysC, TIMP-2/IGFBP-7) and validated in clinical settings, yet few clinical studies have included septic patients. Although some of these biomarkers, especially NGAL and the panel TIMP-2•IGFBP-7, hold promise for early prediction or prognostic information of AKI, their specificity and/or sensitivity for diagnosis of (sepsis-induced) AKI is not optimal.

Technology

Researchers at Ghent University have identified chitinase 3-like protein 1 (CHI3L1) as a specific urinary marker for AKI.

Applications

Assays (kits) for diagnosis, prediction, prognosis, and risk assessment of kidney injury.

Advantages

- Protein biomarker, allowing IVD test development on well-established immuno-assay platforms, including rapid testing formats (such as lateral flow tests).
- Potential for rapid (i.e. upon ICU admission) and specific diagnosis of AKI, in contrast to serum creatinine (SCr) thus contributing to targeted treatment of patients in intensive care.
- Potential complementarity to e.g. (urinary) NGAL, both being true injury biomarkers.

Status of development

Biomarker CHI3L1 was identified in a proteomics study based on a novel model of sepsis-induced AKI in mice, developed at Ghent University. Its specificity was confirmed in Western blot analyses on urine, plasma and renal tissue homogenates of mice. Its translation through clinical validation studies in 3 separate cohorts is finalized for one and in progress for two cohorts. Results on a population of adult intensive care patients (cohort 1, n= 189) are presented.

Partnership

Ghent University is seeking a partner for development and commercialization of the use of UCHI3L1 as (sepsis-induced) AKI biomarker e.g. in combination with UNGAL or other urinary biomarkers.

Intellectual property

A patent application was filed on April 4th 2011. The international patent application has been published as WO2012/136548. Granted European patent EP2694974 and US patent US9410968.

AUC-ROC of UCHI3L1 , UNGAL , and [UCHI3L1]•[UNGAL] 
for prediction of moderate or severe AKI_{Scr}

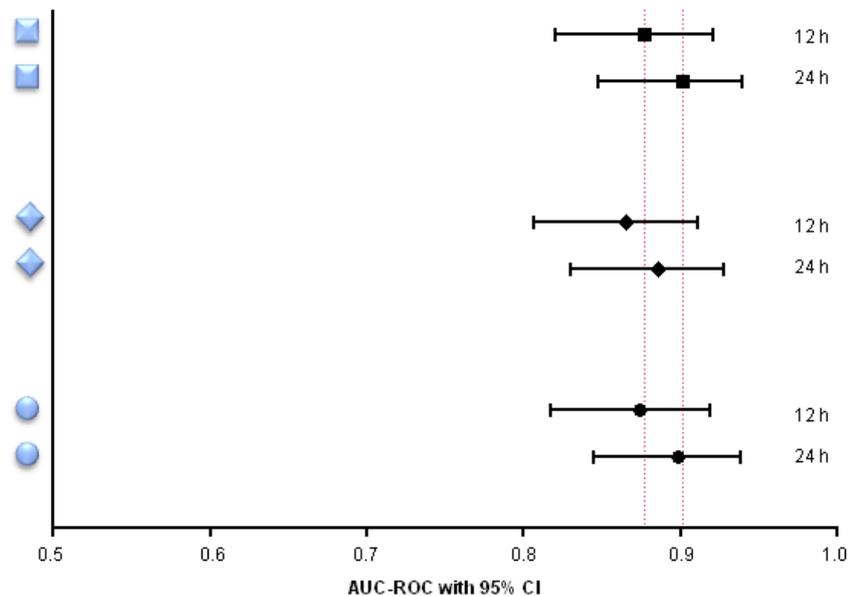


Figure: AUC-ROC with 95% CI (*X-axis*) of UCHI3L1, UNGAL and [UCHI3L1]•[UNGAL] at admission for 12h and 24h endpoints (*Y-axis*).

Abbreviations: AUC-ROC: area under the receiver operating characteristics curve; CI: confidence interval; Scr: serum creatinine; UCHI3L1: urinary chitinase 3-like protein 1; UNGAL: urinary neutrophil gelatinase-associated lipocalin

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