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NEUTROPHIL GELATINASE-ASSOCIATED LIPOCALIN IS ELEVATED IN BILE FROM PATIENTS WITH MALIGNANT PANCREATOBILIARY DISEASE

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Introduction Pancreatobiliary malignancies are amongst the commonest causes of cancer-related death worldwide and usually present with biliary obstruction. Accurate differentiation between benign and malignant causes of obstruction is likely to improve outcome in pancreatobiliary disease and reliable biomarkers are urgently needed. Bile is a potential source of such biomarkers due to its anatomical proximity to the site of pathology. Our aim was to apply a proteomic approach to identify potential biomarkers in bile which could differentiate between malignant and benign disease.

Methods Bile, urine and serum were collected prospectively from 59 patients undergoing ERCP (endoscopic retrograde cholangiopancreatography) for benign (n = 36) or malignant (n = 23) pancreatobiliary disease at our centre. Initially, label-free proteomics and immunoblotting were performed in a sub-set of patients. Candidate biomarkers were selected on the basis of increased abundance of peptide fragments, and immunoblotting performed on an expanded cohort. ELISA was then performed for our potential biomarker on all samples in bile, blood and urine.

Results Neutrophil gelatinase associated lipocalin (NGAL) levels were significantly raised in bile from the malignant disease group, compared to bile from the benign disease group (median 1839 ng/mL vs 472 ng/mL, $p < 0.001$). Biliary NGAL levels had an ROC-AUC of 0.76, specificity 56% and sensitivity 96% for distinguishing malignant from benign causes. Biliary NGAL was independent of serum biochemistry and CA 19-9 in differentiating between underlying benign and malignant disease. NGAL levels were then analysed in other body fluids in the same cohort. No significant differences in serum and urine NGAL levels were found between benign and malignant disease. Combining biliary NGAL and serum CA 19-9 improved diagnostic accuracy for malignancy (sensitivity 85%, specificity 82%, positive predictive value 79%, and negative predictive value 87%).

Conclusion NGAL in bile is a novel potential biomarker to distinguish benign from malignant biliary obstruction, particularly in combination with serum tumour markers.

Competing interests None.

Keywords biliary tract, biomarker, diagnostics, malignancy, proteomics.