Title
Prognostic role of quantitative MRCP-derived biliary metrics in primary sclerosing cholangitis

Background/Rational
Magnetic resonance cholangiopancreatography (MRCP) is essential for diagnosis and follow-up of patients with PSC, but its prognostic performance have been hampered by the semi-quantitative and qualitative nature of the MRI findings which showed a good prognostic performance, but a low-to-moderate inter-observer agreement (1,2).
MRCP+ (Perspectum Ltd., Oxford, UK) is a semi-automated post-processing software that generates a 3D model of the biliary tree and simultaneously provide quantitative measures of biliary tree and gallbladder volume and assess the presence and severity of bile duct strictures and dilatations (3).
The prognostic role of MRCP+ derived metrics have been tested toward clinical outcomes in three proof-of-concept studies and showed promising results (4,5,6). However, the use of MRCP+ metrics for prediction of prognosis remains to be determined in a larger cohort of PSC patients.

Hypothesis/aim
(1) to identify which are the MRCP+ metrics independently associated with adverse-outcome free-survival;
(2) to compare the prognostic value of these metrics with that of already known prognostic factors (ANALI scores, Liver stiffness, Amsterdam-Oxford Model, Mayo risk scores and bilirubin);
(3) to build a prognostic model including these MRCP+ metrics.

Study design
Multicentric retrospective study.
Inclusion criteria: large duct PSC with one MRCP with 3D sequences (the closest to the diagnosis) available for MRCP+ analysis, age > 18 years, minimum follow-up after MRCP of 12 months.
Exclusion criteria: previous episodes of cirrhosis decompensation, previous liver transplant (LT), previous hepatobiliary surgery (except for cholecystectomy), presence, at the time of inclusion or within 6 months after the inclusion, of any of the following conditions: concomitant chronic liver disease (NASH, viral hepatitis, AIH), hepatocellular carcinoma, cholangiocarcinoma.

Endpoints
Liver-related death (including death for cirrhosis decompensation, complications of acute cholangitis or hepatobiliary malignancies), liver transplantation (LT) or date of inscription in waiting list for LT, cirrhosis decompensation

Data collection and variables
i. Demographic, clinical variables and outcome: birth date, weight, height, date of PSC diagnosis, diagnosis of IBD, date of IBD diagnosis, type of IBD, occurrence and date of

occurrence of clinical outcomes [cirrhosis decompensation, death and cause of death, LT and inscription on the waiting list for LT].

ii. Biochemical variables (within 4 weeks from MRCP): total bilirubin, alkaline phosphatase, gamma glutamyl transpeptidase, alanine aminotransferase, aspartate aminotransferase, albumin, platelets count.

iii. Radiological variables: date of MRCP, age at the time of MRCP, gadolinium injection, biliary metrics analyzed by MRCP+™, biliary and gallbladder volume analyzed by MRCP+, Anali score without gadolinium and with gadolinium (calculated by each group), spleen maximum coronal diameter (cm).

iv. Liver stiffness measurement by Fibroscan (+/- 6 months).

Approvals

The centres willing to participate will need to stipulate a DTA (if not yet in place) with Perspectum to upload anonymized images of 3D-MRCP in the Perspectum Portal for the assessment of MRCP+ metrics which will be forwarded to the centres on an excel file.

Saint Antoine Hospital institutional review board approved the review of radiologic data for retrospective study in primary sclerosing cholangitis and informed consent is not required for this retrospective anonymized analysis of radiologic data

Time plan

October 20th, 2022 study start/March 1st, 2023 study end.
Preliminary results will be presented at the next IPSCSG meeting during ILC in Vienna.
Publication of results 2nd half 2023/1st half 2024.

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