

Oral Cholate Challenge Test Characterizes Functional Differences between Child-Pugh A5 and A6

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Background & Aims

- Liver function in patients with Child-Pugh (CP) A cirrhosis may vary from normal to severe functional impairment and shunting.
- Staging disease severity in patients with CP A cirrhosis is important for clinical decisions regarding further diagnostic testing, treatment, or follow-up interval.
- We used the oral cholate challenge test (HepQuant DuO[®]) to characterize and compare patients with CP A5 and A6.

Methods

- 454 subjects with CP A cirrhosis in two prospective studies linking cholate challenge test to EGD findings:¹
 - SHUNT-V (n=238)
 - HALT-C (n=216)
- Standard laboratory values included albumin, alkaline phosphatase, ALT, AST, bilirubin, INR, and platelet count.

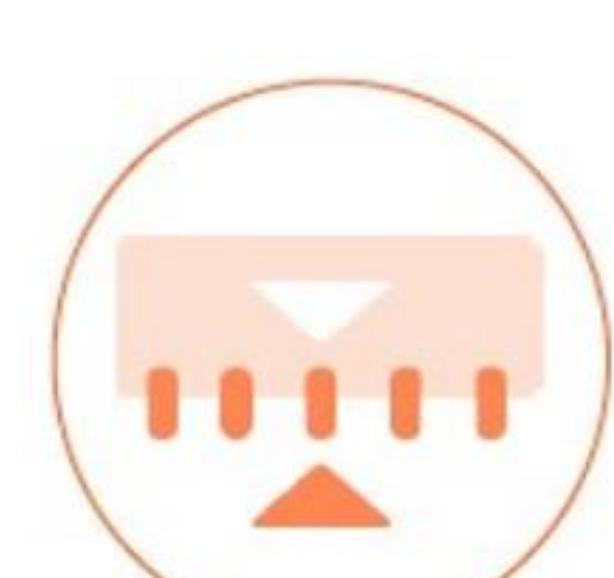
HepQuant DuO[®] Test:²⁻³



1. Oral d4-cholate



2. Draw blood at 20 & 60 min.



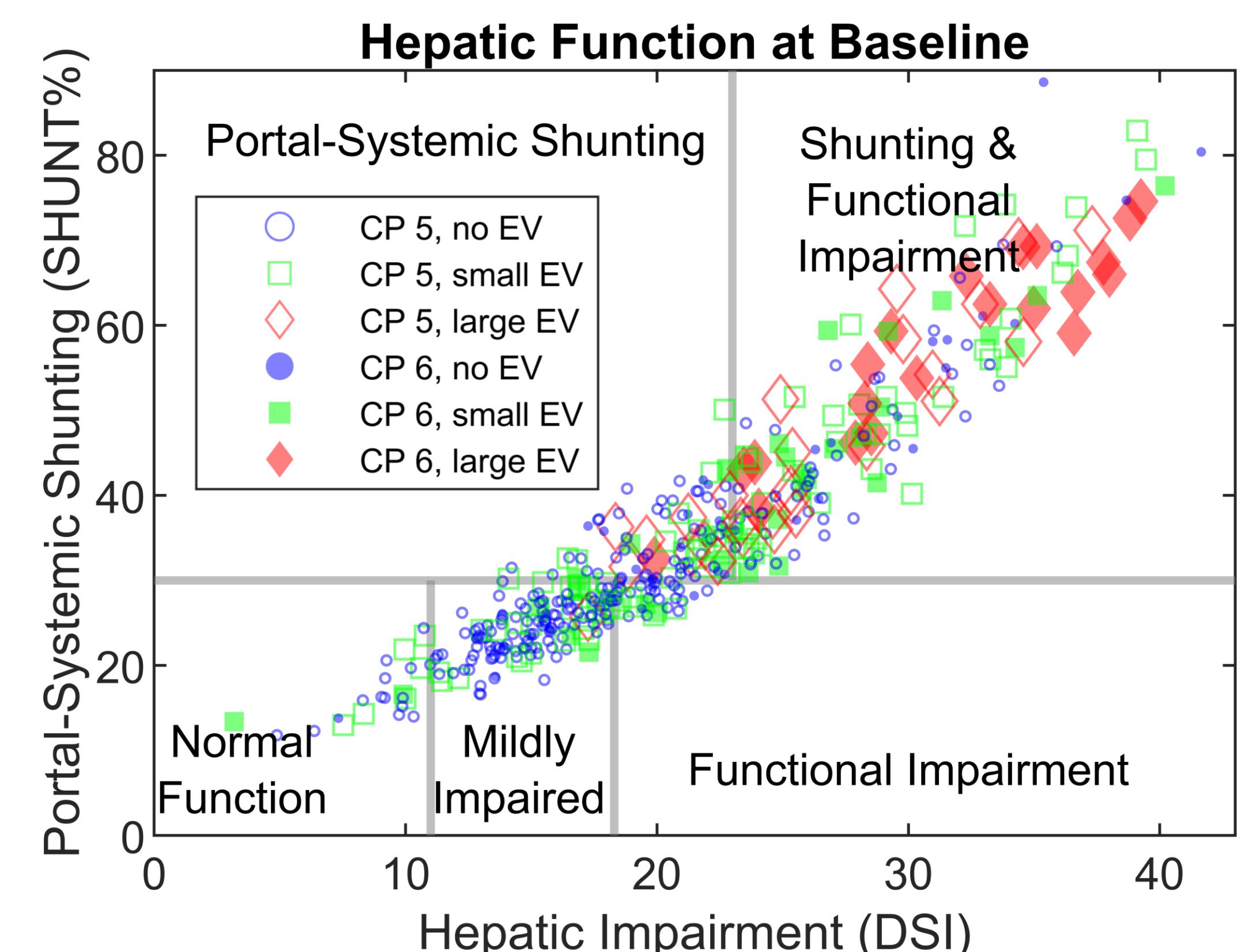
3. Analyze samples by LC-MS/MS



4. Report DSI, SHUNT%, Hepatic Reserve (HR%), Hepatic Filtration Rates (HFR)

Results

- Hepatitis C was more prevalent and MASLD/MASH less prevalent in CP A6.
 - Prevalences of ALD and obesity similar between CP A5 & A6.
 - 28% had small esophageal varices (EV), 11% had large EV.
- Subjects with CP A6 were more likely to have large EV (23%) compared to CP A5 (8%) ($p=0.0001$).
- HepQuant DuO showed worse function and shunting in subjects with CP A6 ($p<0.0001$).
- AUROCs for large EV for all HepQuant DuO test parameters (0.82-0.83) were significantly higher than CP score (0.63) ($p<0.0001$).



| | CP A5 (n=361) | CP A6 (n=93) | P value |
|--|---------------|--------------|---------|
| Age, years | 56.5 ± 10.5 | 54.2 ± 11.3 | 0.06 |
| Male | 222 (61.5%) | 54 (58.1%) | 0.63 |
| Lab values & scores | | | |
| Albumin, g/dL | 4.2 ± 0.4 | 3.5 ± 0.4 | <0.001 |
| Alk. Phos., U/L | 95.9 ± 45.4 | 119.6 ± 49.2 | <0.001 |
| ALT, U/L | 70.8 ± 76.5 | 77.3 ± 59.4 | 0.45 |
| AST, U/L | 59.1 ± 51.2 | 82.8 ± 49.0 | 0.001 |
| Bilirubin, mg/dL | 0.7 ± 0.3 | 1.0 ± 0.5 | <0.001 |
| INR | 1.0 ± 0.1 | 1.1 ± 0.2 | <0.001 |
| Platelets, ×10 ³ µL ⁻¹ | 164 ± 67 | 131 ± 63 | <0.001 |
| MELD score | 7.1 ± 1.6 | 8.3 ± 2.6 | <0.001 |
| HepQuant DuO | | | |
| DSI | 19.8 ± 6.4 | 25.2 ± 7.9 | <0.001 |
| SHUNT%, % | 33.0 ± 12.4 | 43.8 ± 16.7 | <0.001 |
| Hepatic Reserve, % | 78.5 ± 16.2 | 64.2 ± 19.8 | <0.001 |
| HFR, mL/min/kg | 13.2 ± 6.9 | 9.2 ± 7.5 | <0.001 |

Conclusions

- Patients with CP A6 cirrhosis have worse hepatic function and more portal-systemic shunting than patients with CP A5 cirrhosis.
- HepQuant DuO allowed characterization of functional differences in CP A5 versus A6 and was more predictive for EV than CP score.
- Given the heterogeneity within the CP classification, HepQuant DuO may be useful clinically in staging disease severity.

Disclosures

MPM is a paid consultant for HepQuant, LLC. JCI and GTE are employees and equity member of HepQuant, LLC. MPM and GTE have patents pending. HepQuant DuO is a Laboratory Developed Test (LDT) and is not FDA approved. Test results should be used together with other clinical or laboratory information or results to inform the provider's decisions regarding procedures, treatments, or interventions.

References

- [1] Hassanein et al. *Aliment Pharmacol Ther* 2024.
- [2] McRae et al. *Clin Transl Sci* 2024.
- [3] McRae et al. *Basic Clin Pharmacol Toxicol* 2024.



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