THE HEPQUANT SHUNT TEST PREDICTS THE LIKELIHOOD OF FINDING ESOPHAGEAL VARICES AND PARTICULARLY LARGE VARICES AT ENDOSCOPY



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Patient Characteristics at Baseline

Background

- Large esophageal varices are an ominous complication of advanced chronic liver disease due to risk for variceal hemorrhage and clinical decompensation.
- When detected, large esophageal varices require treatment.
- Small esophageal varices require surveillance.
- The linkage of HepQuant SHUNT testing to varices was suggested in the US multicenter HALT-C study and recently evaluated in the US multicenter SHUNT-V study.

Aim

The aim was to define the association of parameters of the HepQuant SHUNT test to endoscopic findings of large esophageal varices.

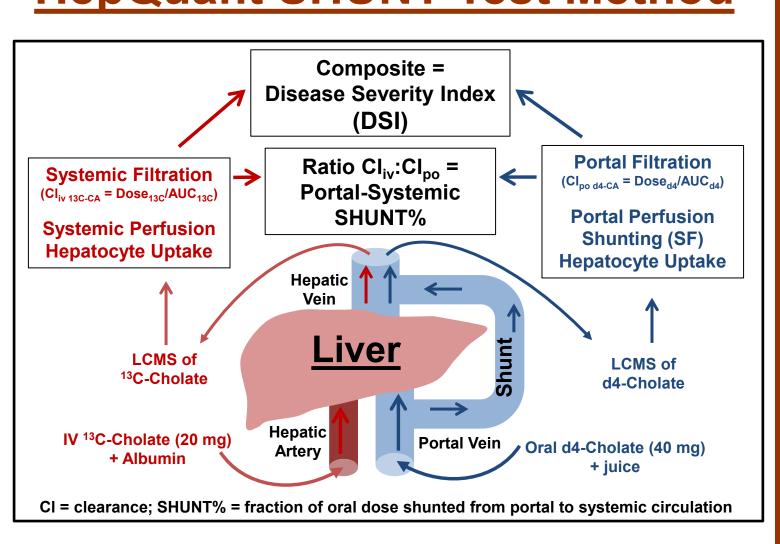
Specifically, we examined the relationships of HepQuant's Diseases Severity Index (DSI), and SHUNT% to

- Large esophageal varices
- Any esophageal varices

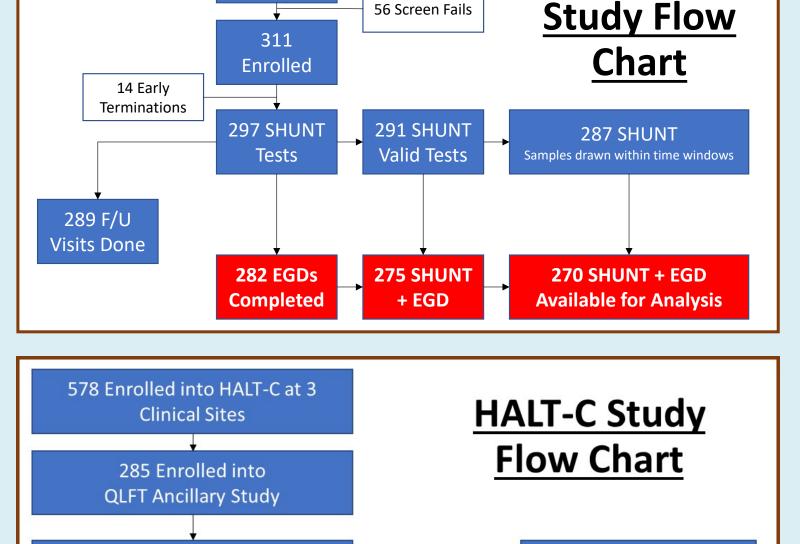
Subject Inclusion/Exclusion

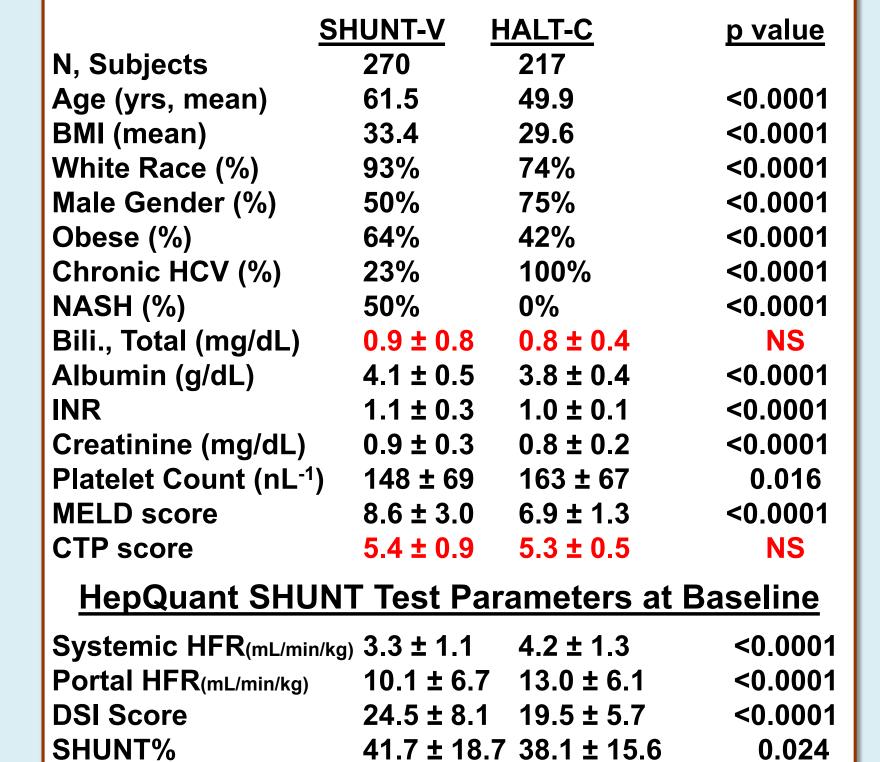
- Clinical Sites: 3 in Halt-C (N=217); 27 in SHUNT-V (N=270)
- Advanced Liver Fibrosis (both studies)
- Compensated Cirrhosis (both studies)
- Clinically stable Child-Pugh B cirrhosis (SHUNT-V only)
- Exclusion: Prior variceal hemorrhage (both studies)
- Exclusion: Prior diagnosis of large varices (SHUNT-V)

HepQuant SHUNT Test Method



Results





<0.0001

STAT (μ M per 75 kg weight) 1.71 ± 1.62 1.14 ± 0.75

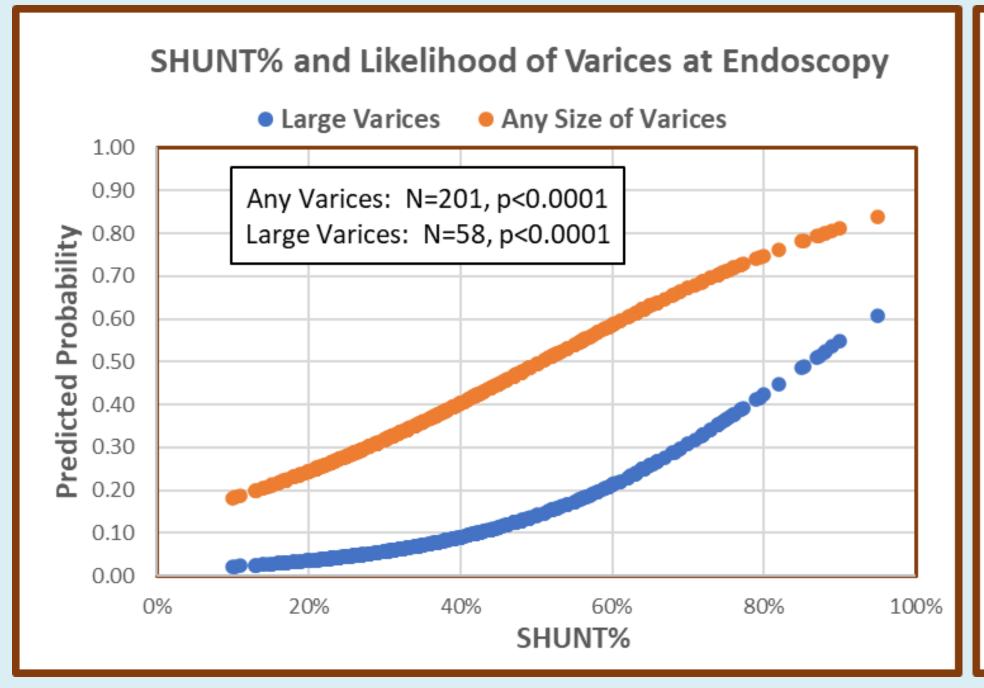
Relationship of SHUNT% (Left Panel) and DSI (Right Panel) to Likelihood of Large Varices or Any Size Varices was Highly Significant (both studies combined, N=487)

SHUNT-V

Long-Term Followup

217 SHUNT + EGD

Available for Analysis

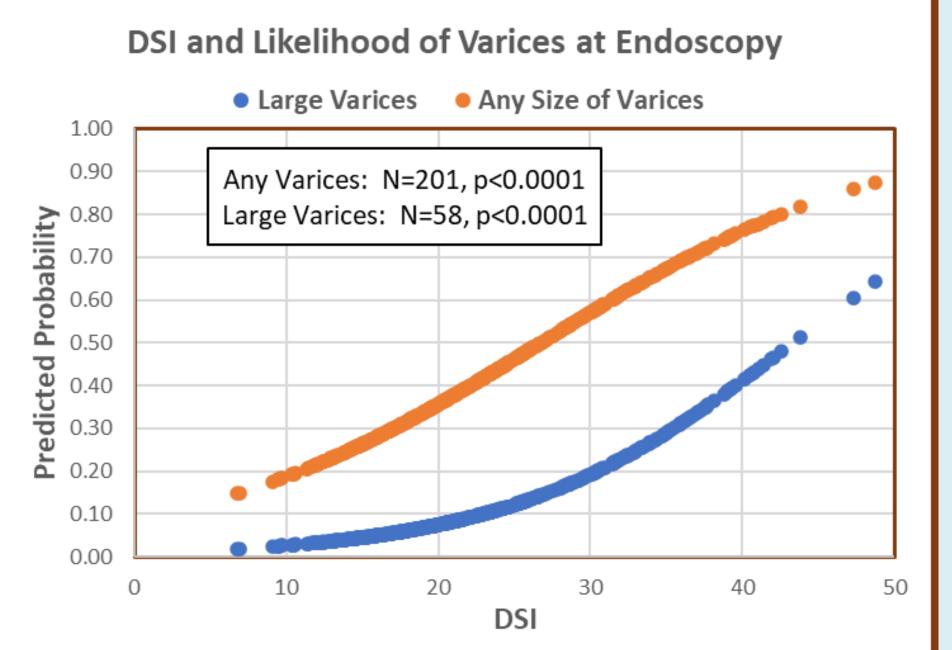


277 SHUNT Tests

Analyzed by LC/MS

32 Achieved SVR

25 Early Termination



Conclusions and Key Takeaways

- The HepQuant DSI and SHUNT% predict the likelihood of finding esophageal varices, particularly large varices, at endoscopy across a wide spectrum of patient characteristics, disease etiologies, and severity of CLD.
- The HepQuant SHUNT may be useful in the decision to avoid or proceed with endoscopic screening or surveillance.

References

- 1. Everson, G.T., et al., Portal-systemic shunting in patients with fibrosis or cirrhosis due to chronic hepatitis C: the minimal model for measuring cholate clearances and shunt. Alimentary pharmacology & therapeutics, 2007. 26(3): p. 401-10.
- 2. Everson, G.T., et al., The spectrum of hepatic functional impairment in compensated chronic hepatitis C: results from the Hepatitis C Anti-viral Long-term Treatment against Cirrhosis Trial. Aliment Pharmacol Ther, 2008. 27(9): p. 798-809.
- 3. Everson, G.T., et al., Quantitative liver function tests improve the prediction of clinical outcomes in chronic hepatitis C: results from the Hepatitis C Antiviral Long-term Treatment Against Cirrhosis Trial. Hepatology, 2012. 55(4): p. 1019-29.
- 4. Burton, J.R., Jr., et al., The within-individual reproducibility of the disease severity index from the HepQuant SHUNT test of liver function and physiology. Translational research: the journal of laboratory and clinical medicine, 2021.
- 5. Fallahzadeh, M.A., et al., Predicting clinical decompensation in patients with cirrhosis using the HepQuant-SHUNT test. Alimentary pharmacology & therapeutics, 2021. 53(8): p. 928-938.
- 6. Wieland, A., et al., HepQuant SHUNT Detects Portal Hypertension in Early Stages of Clinically Compensated Chronic Liver Disease. Clinical gastroenterology and hepatology: the official clinical practice journal of the AGA, 2021.
- 7. Ghaziani, T.T. and P.Y. Kwo, How clinicians may use tests of hepatic function now and in the future. Translational research: the journal of laboratory and clinical medicine, 2021.

Disclosures

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