Endoscopic Ultrasound-Guided Portosystemic Pressure Gradient Measurements vs. Transjugular Balloon Occlusion Measurement: A Multicenter EU
Study

Published: 10-03-2023
Last updated: 06-04-2024

The primary study objective is to evaluate the correlation of the calculated portosystemic pressure gradient (PPG) obtained by direct portal and hepatic pressure measurements with the EchoTip® systemic Pressure Gradient (EchoTip® InsightTM) and...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON56366

Source
ToetsingOnline

Brief title
ENCOUNTER (EU)

Condition

- Other condition
- Hepatic and hepatobiliary disorders

Synonym
increased venous liver pressure, scarring of the liver

Health condition

liver cirrhosis, portal hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Cook Research Incorporated
Source(s) of monetary or material Support: Cook Research Incorporated

Intervention

Keyword: liver venous pressure measurements, medical device, post-market study

Outcome measures

Primary outcome

The primary measure is the evaluation of the correlation between the calculated PPG obtained using the EchoTip® Insight and the HVPG procedure performed under general anesthesia.

Secondary outcome

The secondary measures are:

1. Comparison between calculated PPG obtained by EchoTip® Insight and mild sedation HVPG

2. HVPG measurement performed under mild sedation compared to the HVPG measurement under general anesthesia

3. Direct portal vein pressure measurement obtained by the EchoTip® Insight compared to the transjugular WHVP measurement obtained during an IR (Interventional Radiology) procedure under mild sedation and general anesthesia

4. Direct hepatic vein pressure measurement obtained by the EchoTip® Insight

compared to the transjugular FHVP measurement obtained during an IR procedure under mild sedation and general anesthesia

5. Evaluation of technical success (see Definitions section in the protocol)

6. Evaluation of the association between EchoTip® insight measurements and the degree of clinical features of portal hypertension. At minimum, the following will be evaluated to determine whether there is clinical significance between EchoTip® Insight measurements and HVPG measurements and clinical presentation including:

a. Presence of gastric or esophageal varices

b. Portal hypertensive gastropathy

c. Thrombocytopenia

d. Child-Pugh score

e. MELD score

f. Liver elasticity (if available within 1 year prior to procedure)

7. All EchoTip® -related adverse events (see Definitions section in the protocol)

For patients receiving a transjugular intrahepatic portosystemic shunt (TIPS) (see Definitions section in the protocol) only:

8. Direct portal vein pressure measurement obtained by the EchoTip® insight compared to the transjugular direct portal vein measurement obtained during an IR procedure (only in patients undergoing a TIPS procedure)

Study description

Background summary

Measurements of the venous blood pressure in the liver provides the study doctor with important clinical information to develop a treatment plan for patients diagnosed with cirrhosis. The conventional method for measurement of vascular blood pressure in the liver is HVPG, where direct free (FHVP) and wedged (WHVP) hepatic vein pressure measurements are obtained. However, HVPG provides an indirect measurement and can be burdensome to the patient. The EchoTip® Insight* device provides a direct measurement of the vascular blood pressure in the liver and can be less burdensome for the patient.

Study objective

The primary study objective is to evaluate the correlation of the calculated portosystemic pressure gradient (PPG) obtained by direct portal and hepatic pressure measurements with the EchoTip® systemic Pressure Gradient (EchoTip® InsightTM) and indirect portal vein pressure measurements using the interventional radiology based hepatic venous pressure gradient (HVPG) procedure where direct free (FHVP) and wedged (WHVP) hepatic vein pressure measurements are obtained.

Study design

The study is an international, multicenter, prospective, clinical post-market study.

Intervention

See also pages 28-30 of the protocol and schedule in the protocol on page 12.

Non-TIPS patients
1. Mild sedation: To control for possible variations in portal pressure due to the influence of anesthetic agents, a first set of HVPG measurements will be undertaken under mild sedation in accordance with standard of care. During the HVPG procedure, HVPG will be calculated, using standard balloon occlusion measurement techniques, as is the standard of care for this procedure (FHVP and WHVP each in triplicate).
2. General anesthesia: After this first set of measurements, the patient will receive propofol general anesthesia, which will be maintained by an anesthesiologist throughout the procedure. The patient will be intubated and mechanically ventilated.
3. Concomitantly, the EchoTip® Insight and HVPG measurements will begin. The EchoTip® Insight measurements are performed as described below by the endoscopy physician. This will be coordinated with the center's IR (Interventional Radiology) department performing the HVPG procedure. The physician performing HVPG and the endoscopy physician performing EchoTip® measurements will be

strongly encouraged not to share results taken by the other physician. If possible, the hepatic vein pressure measurements using both the techniques should be obtained within the same hepatic vein.
The endoscopy physician will begin the EchoTip® Portosystemic Pressure Gradient measurement (the study procedure see Definitions) in conjunction with the HVPG measurements performed by the IR physician.
a. First, an esophagogastroduodenoscopy and an EUS will be performed to evaluate for exclusion criteria. If no exclusion criteria are met, the EchoTip® Insight procedure and calculations will be carried out as described in the IFU (Instructions for use).
b. Briefly described, the EchoTip® Insight Needle will be introduced into the accessory channel of the endoscope and will be placed across the stomach or duodenal wall and through the liver parenchyma into the portal and hepatic vein under EUS guidance.
c. Three separate pressure readings will be obtained by the EchoTip® Insight while the EchoTip® is located in each of the target vessels, flushing the catheter between each reading (up to 0.5 ml). For the hepatic vein pressure measurements, it is recommended to obtain these pressure measurements using both techniques in the same hepatic vein concomitantly.
d. The EchoTip® needle will then be retracted to the sheath and removed. The study procedure has ended.

TIPS patients
1. Mild sedation: To control for possible variations in portal pressure due to the influence of anesthetic agents, a first set of HVPG measurements will be undertaken under mild sedation in accordance with standard of care. During the HVPG procedure, HVPG will be calculated, using standard balloon occlusion measurement techniques, as is the standard of care for this procedure (FHVP and WHVP each in triplicate).
2. General anesthesia: After this first set of measurements, the patient will receive propofol general anesthesia, which will be maintained by an anesthesiologist throughout the procedure. The patient will be intubated and mechanically ventilated.
3. Concomitantly, the EchoTip® InsightTM and HVPG measurements will begin as outlined above. If possible, the hepatic vein pressure measurements using both the conventional HVPG and EchoTip® InsightTM should be obtained within the same hepatic vein. The WHVP and FHVP using the HVPG technique and the direct hepatic vein pressure measurement using the EchoTip® InsightTM will be obtained in triplicate. Physicians performing measurements are strongly encouraged not to share any results.
4. Free portal vein pressure will be measured using the IR technique during the TIPS procedure before performing an angioplasty and dilating the hepatic tract.
5. The TIPS procedure can proceed as standard of care after completion of the EchoTip® InsightTM pressure measurements.

Study burden and risks

This is extensively described in the protocol, paragraph 6.0 (Risk Analysis and Risk Assessment), page 17-20.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with cirrhosis who have been referred for a procedure where HVPG is obtained.

Exclusion criteria

General criteria:

1. Patient is < 18 or > 85 years of age
2. Patient is pregnant, breast-feeding, or planning to become pregnant during the
course of the study
3. Patient is unwilling or unable to sign and date the informed consent
4. Patient is unwilling to comply with the follow-up study schedule
5. Patient for whom endoscopic procedures are contraindicated
6. Patients for whom propofol general anesthesia is contraindicated

Medical criteria:
7. Platelet count <50,000 per mm3
8. International normalized ratio (INR) > 1.7
9. Estimated glomerular filtration rate (eGFR) (see Definitions section) < 50
mL/min/1.73m2
10. Previous transjugular intrahepatic or surgical portosystemic shunt
11. Previous total or partial splenectomy
12. Non-cirrhotic portal hypertension
13. Known history of spontaneous bacterial peritonitis (SBP) within the last
three months irrespective of treatment for SBP
14. Patients with known infection which is not controlled by medical
intervention
15. Portopulmonary hypertension
16. Cardiac decompensation
17. Pre-sinusoidal liver disease
18. Cholestatic liver disease
19. Patient who received endoscopic treatment for upper gastrointestinal (GI)
variceal bleeding within the past 7 days
20. Patients with current hepatocellular carcinoma (HCC)

Anatomical (identified at screening and/or during the endoscopic procedure)
criteria:
21. Portal vein thrombosis
22. Anatomic abnormalities of the hepatic vasculature that prevent access to
the intrahepatic
portion of the portal vein or hepatic veins
23. Evidence of active GI bleeding
24. If the volume of ascites in the path of the needle prevents apposition of
the gastrointestinal
tract and liver

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	9
Type:	Anticipated

Medical products/devices used

Generic name:	EchoTip® Insight
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	10-03-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT04987034
CCMO	NL80037.078.22