Portal Pressure in Heart Failure PoP-HF: a pilot study

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Primary Objective: 1. To provide data on portal pressure in a heart failure (HF) cohort without substantiated hepatopathySecondary Objective(s): 1. To provide data on the hepatic venous pressure gradient in a HF cohort without substantiated...

Ethical review	Approved WMO
Status	Pending
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON57225

Source
ToetsingOnline

Brief title
PoP-HF

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
cardiac failure, heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: afdeling cardiologie UMCG

Intervention

Keyword: Heart failure, Kidney, Pancreas, Portal pressure

Outcome measures

Primary outcome

The primary outcome concerns the portal pressure gradient (HPVG).

HVPG represents the difference between the wedged hepatic venous pressure (WHVP) and the free hepatic venous pressure (FHVP). The WHVP is measured by occluding the right hepatic vein through the inflation of a balloon, whereas FHVP is measured without occluding it.

The normal HVPG value is between 1 to 5 mmHg. A figure above this range indicates elevated portal pressure. According to their prognostic value, patients with portal hypertension can be classified in two main groups: mild or subclinical (>=6 to 9 mmHg) and clinically significant portal hypertension (>=10 mmHg).

Secondary outcome

- The association between the portal pressure gradient (HPVG) and renal function (eGFR)

- The association between HPVG and fecal elastase (FE-1)/presence of exocrine pancreas insufficiency (EPI)

- The association between HPVG and other hemodynamic indices (pulmonary capillary wedge pressure (PCWP), right atrial pressure (RAP), pulmonary arterial pressure (PAP) obtained during cardiac catheterization.

Study description

Background summary

Heart failure (HF) is a complex clinical syndrome due to a structural and/or functional abnormality of the heart that results in elevated intracardiac pressures and/or inadequate cardiac output at rest or during exercise. The pathophysiology of HF progression is complex and consists of hypoperfusion and unrestrained neurohormonal up-regulation, sympathetic activation and systemic congestion. Abdominal congestion manifests in a substantial proportion of HF patients and there is increasing evidence for its role of the disease progression and derangement.

The abdominal, *splanchic*, venous system is the largest reservoir in the human body. Splanchnic veins are extremely compliant and responsive to sympathetic and angiotensin modulation and thus capable of buffering changes in circulating blood volume. In HF, due to longstanding congestion and neurohormonal activation, this system becomes maladaptive, resulting in redistribution of effective circulatory volume and increased cardiac filling pressures, aggravating decompensated (acute) HF.

The splanchnic circulation drains into the portal system, entailing that, in the absence of (cirrhotic) liver disease, portal pressures are directly related to venous pressure in the abdominal compartment and vice versa. To our knowledge, no studies evaluating portal pressure in a HF population without (suspected) hepatopathy exist. This is striking given the increasing emphasis on abdominal congestion in HF and the clinical deterioration (inflammation, electrophysiological abnormalities, and malnutrition) associated with portal hypertension. Additionally, right sided pressures are the most significant predictor of cardiac cachexia (8) and (independently) related to dysfunction of abdominal organs such as the kidney, intestine and pancreas. This leads us to believe portal hypertension, perhaps more than central venous hypertension, is capable of driving organ dysfunction in HF.

Data concerning the association between splanchnic and systemic hemodynamics and clinical status/organ dysfunction would provide new insight into the role of the abdominal compartment in (congestive) HF. The aim of this study is to provide hemodynamic measurements of portal pressure in HF and to relate this to clinical surrogates and organ (dys)function. We are specifically interested in the impact of portal pressure on the kidney and pancreas. *

Study objective

Primary Objective:
1. To provide data on portal pressure in a heart failure (HF) cohort without substantiated hepatopathy

Secondary Objective(s):
1. To provide data on the hepatic venous pressure gradient in a HF cohort without substantiated hepatopathy
2. To relate portal pressure to renal functioning in a HF cohort without substantiated hepatopathy
3. To relate portal pressure to exocrine pancreatic function in a HF cohort without substantiated hepatopathy
4. To relate portal pressures to central right/left sided hemodynamic parameters

Study design

This concerns a cross-sectional, single center, pilot study. Patients undergoing right cardiac catheterization for the evaluation of HF will be included and for this study additional measurements of portal pressure are performed. In the UMCG this includes patients with advanced HF who are screened for mechanical circulatory support or transplantation, patients with (suspected) heart failure with preserved ejection fraction (HFpEF) in whom cardiac (filling) pressure are evaluated and patients with congenital cardiac disease for hemodynamic evaluation.
Right heart catheterization in the UMCG is performed by introduction of a sheath and Swan-Ganz catheter through the femoral or jugular vein under local anesthesia. For this study additional measurements of portal pressure are performed by advancing the (abovementioned) small balloon catheter under X-ray guidance into the hepatic vein. The wedged hepatic venous pressure (WHVP) is obtained by inflating a balloon, thereby blocking blood flow. This pressure represents the transmission pressure from the portal vein. Afterwards the balloon is deflated and free hepatic venous pressure (FHVP) is measured. The gradient between the FHVP and WHVP is equal to the portal pressure gradient (HPVG). A total of 30 subjects will be included in this pilot study. A total of 30 subjects will be included in this pilot study.

Study burden and risks

A benefit is that subjects will be provided additional information concerning portal pressure and pancreas/renal function.
No additional risks are associated with the measurements required for this study. The disadvantage is that the catheterization could take more time (approximately 5 minutes) that this could be associated with slight additional radiation, and that fecal sampling is required.

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

- Age >= 18 years
- Give written informed consent
- Scheduled for right heart catheterization for analysis of heart failure

Exclusion criteria

- Substantiated liver disease or dysfunction including ASAT and/or ALAT > 3x the upper limit of normal (ULN)
- Currently requiring dialysis or estimated GFR <20 ml/min/1.73 m2 by CKD-Epi equation
- Pancreatic diseases, including acute pancreatitis, chronic pancreatitis and pancreatic cancer
- Congenital metabolic disease
- Cystic fibrosis
- Pregnancy

- (Suspected) constrictive pericarditis
- Suspected pulmonary hypertension associated primarily with hypoxia and lung disease (group 3 pulmonary hypertension)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2024
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	12-12-2024
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL86332.042.24