

BMJ Open Incidence, management and outcomes in hepatic artery complications after paediatric liver transplantation: protocol of the retrospective, international, multicentre HEPATIC Registry

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ABSTRACT

Introduction Hepatic artery complications (HACs), such as a thrombosis or stenosis, are serious causes of morbidity and mortality after paediatric liver transplantation (LT). This study will investigate the incidence, current management practices and outcomes in paediatric patients with HAC after LT, including early and late complications.

Methods and analysis The HEPatic Artery stenosis and Thrombosis after liver transplantation In Children (HEPATIC) Registry is an international, retrospective, multicentre, observational study. Any paediatric patient diagnosed with HAC and treated for HAC (at age <18 years) after paediatric LT within a 20-year time period will

be included. The primary outcomes are graft and patient survivals. The secondary outcomes are technical success of the intervention, primary and secondary patency after HAC intervention, intraoperative and postoperative complications, description of current management practices, and incidence of HAC.

Ethics and dissemination All participating sites will obtain local ethical approval and (waiver of) informed consent following the regulations on the conduct of observational clinical studies. The results will be disseminated through scientific presentations at conferences and through publication in peer-reviewed journals.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The HEPatic Artery stenosis and Thrombosis after liver transplantation In Children Registry will be the multicentre, retrospective, observational study investigating the incidence of hepatic artery complication (HAC) in patients after paediatric liver transplantation.
- ⇒ The multicentre approach allows us to investigate the current management practices internationally, including the experience of centres, centre protocols for anticoagulant therapy and diagnostic protocols for HAC.
- ⇒ The study will evaluate different management strategies for HAC, including conservative management, surgical and endovascular revascularisation and retransplantation, on both patient and graft survival.
- ⇒ The retrospective observational nature of this multicentre study and variations in HAC management and definition may limit generalisability. Therefore, prospective studies will follow to further validate the findings.

Trial registration number The HEPATIC registry is registered at the ClinicalTrials.gov website; Registry Identifier: [NCT05818644](https://clinicaltrials.gov/ct2/show/study/NCT05818644).

INTRODUCTION

Excellent outcomes of liver transplantation (LT) have made it the primary treatment option for paediatric patients with advanced liver disease and liver failure.¹ However, hepatic artery complications (HACs) remain a common problem despite advances in LT techniques. In children, the reported prevalence rates of HAC range from 1.7% to 16.3%, which are higher than in adults and affect both patient and graft survival as well as quality of life after LT.²

Hepatic artery thrombosis (HAT) is the most frequently reported HAC in paediatric LT, frequently leading to graft loss and early retransplantation.³ Hepatic artery stenosis (HAS) is the second most reported HAC, and if left untreated, may progress to HAT, leading to graft failure, biliary complications and even death.^{4,5} Previous studies have reported incidence rates of 5% for HAS and 8.3% for HAT in paediatric patients who undergone LT.^{6–8} However, these rates are derived from single-centre studies and are specific to certain risk groups, such as those with young age at LT, retransplantation and a non-cirrhotic metabolic disease as the primary disease. The incidence rates in other risk groups are unknown. Additionally, the incidence of HAC is influenced by the screening protocol and preventive anticoagulation therapy after transplantation.⁶

The optimal management strategy for HAC remains uncertain, and the effectiveness of different treatment modalities, such as conservative management, surgical or endovascular treatment and retransplantation is unknown.^{6,9} To bridge this knowledge gap, we designed the HEPatic Artery stenosis and Thrombosis after liver transplantation In Children (HEPATIC) Registry.

This multicentre, retrospective, observational study aims to determine the effectiveness of all treatment strategies for HAC after paediatric LT and evaluate current

management practices, including anticoagulant therapy, screening protocols and assessment criteria across participating centres. The study will also determine the overall incidence of HAC after paediatric LT.

METHODS AND ANALYSIS**Study objectives****Primary objective**

The primary objective of this registry will be to evaluate the effectiveness of various treatment strategies, including conservative management (observation or pharmacotherapy), surgical interventions, endovascular procedures and retransplantation for HAC in paediatric patients after LT.

Secondary objectives

The secondary study objective is to investigate primary and secondary patency of the hepatic artery after interventions for HAC, intraprocedural and postprocedural complications, as well as the current management practices and number of procedures per centre. Additionally, the study aims to examine anticoagulant therapy protocols, diagnostic protocols, and assessment criteria as well as the overall incidence of HAC.

Study design and population

This retrospective, multicentre, observational study will investigate HAC after paediatric LT. HAT is defined as a complete occlusion of (a part of) the hepatic artery, and HAS is defined as an abnormal narrowing of the hepatic artery leading to decreased perfusion to the liver. The determination of haemodynamic significance is not predefined, as there are multiple definitions within the current literature. Patients are eligible for inclusion if the following criteria are met: (1) LT between 1 January 2002 and 1 January 2022, and diagnosis of an HAC after LT, (2) the age of the patient is <18 years at the time of HAC diagnosis or intervention and (3) the date of diagnosis of HAC or intervention was before 1 January 2023. The requirement of informed consent was evaluated on a centre-by-centre basis, in accordance with local regulations and ethical guidelines. HAC occurring after a first or subsequent LTs will be included. Multiple HAC per patient can be reported as distinct events. Patient and graft survival for each HAC record will be calculated and reported for the HAC index LT (the LT after which the HAC occurred).

Data collection

Data will be collected from the medical records of all patients who undergo paediatric LT at each participating site. Patient demographics, information regarding the underlying disease, symptoms, treatment and outcomes will be gathered (online supplemental appendix 1).

The study will include the following treatments: conservative (anticoagulation, systemic thrombolysis, wait-listing for retransplantation and hyperbaric oxygen therapy),

surgical revascularisation (reoperation with all types of thrombectomy, gastroduodenal artery or splenic artery ligation and redo of arterial anastomosis or reconstruction), endovascular revascularisation (catheter-directed thrombolysis, percutaneous transluminal angioplasty, with or without a stent, and splenic artery embolisation) and retransplantation.

The management practices currently used at each participating site will be assessed, including the arterial anastomosis techniques, routine anticoagulant therapy, preventive measures, screening protocol, diagnostic criteria, number of procedures and radiological follow-up after transplantation and treatment. The questionnaire used to gather information about these practices is listed in online supplemental appendix 2.

Additionally, data regarding the number of paediatric LTs performed between 1 January 2002 and 1 January 2022 will be collected, including subgroup information such as the time period of LT, age at LT, indication for LT, donor type (living or deceased liver donor) and type of liver graft (whole liver vs partial/split liver graft).

Outcome measures

Graft and patient survival

Graft survival is defined as a functioning graft from transplantation to the end of follow-up data, retransplantation or death, whichever occurs first. Patient survival is defined from the date of the primary LT until date of death. Causes of retransplantation or death will be recorded. Kaplan-Meier curves will be plotted to visualise patient and graft survival rates at various times after transplantation, including 1, 3, 5, 10, 15 and 20 years.

Secondary outcomes

Technical success

Technical success is defined as the success of the intervention in re-establishing the arterial blood flow to the liver and will be assessed by each individual centre.

Primary and secondary patency

Primary patency is defined as the time between the index treatment and reintervention intended to restore patency in patients with a restenosis or reocclusion. Secondary patency is the time between the index treatment and failure to re-establish flow by means of reintervention. In case of retransplantation or death due to other reasons, the patients will be censored if the treated vessel is patent. Kaplan-Meier curves will be plotted to visualise primary and secondary patency rates at various times after treatment for HAC, including 1, 3, 5, 10, 15 and 20 years.

Intraprocedural and postprocedural complications

Procedural complications will be categorised into two main groups: transplant complications and procedural complications related to endovascular or surgical revascularisation for HAC. Within these groups, intraprocedural complications predominantly consist of vascular issues, such as thrombosis, stenosis, compression, dissection and rupture. In contrast, postprocedural complications

encompass a broader range of issues, such as infection, rejection, bleeding and vascular and biliary complications, including anastomotic stricture, non-anastomotic strictures, bile leak, biloma or cholangitis. Reinterventions addressing both intraprocedural and postprocedural complications will also be recorded.

Anticoagulant therapy after transplantation and after interventions

Anticoagulant therapy after transplantation and after interventions for HAC will be assessed according to the management practices of each participating site (centre specific) and individual patient data (patient specific). Details about each anticoagulation regimen, including the specific anticoagulant, duration of anticoagulation and upper and lower limits of target values, such as international normalised ratio, anti-factor Xa and activated partial thromboplastin time, will be recorded. Patient-specific management will be documented for patients with HAC.

Centre-specific screening protocol, diagnostic criteria and radiological follow-up

Local screening protocols to assess HAC after LT, such as the routine postoperative Doppler ultrasound policy, will be documented. Whether HAC screening is consistent for patients with and without risk factors will also be examined. The frequency of preferred radiological screening investigations within 2 weeks after LT will be determined, considering various risk factors.

The Diagnostic criteria section will cover the types of HAC, non-invasive radiological criteria and interventional radiological criteria during invasive angiography. The centre's definition of technical success after interventional radiological treatment will also be recorded.

The radiological follow-up section will assess whether follow-up protocols are the same for all interventions or specific to each intervention type. The imaging methods and frequencies of radiological follow-up for different treatment modalities will be determined.

Incidence

The incidence of HAC will be determined by dividing the total number of patients diagnosed with HAC between 1 January 2002 and 1 January 2023, who had undergone LT between 1 January 2002 and 1 January 2022, by the total number of patients who underwent LT at paediatric age between 1 January 2002 and 1 January 2022. The study will present the overall incidence of HAC during the 20-year period of 2002–2022, as well as the incidence during specific 5-year intervals, namely 2002–2007, 2007–2012, 2012–2017 and 2017–2022, for each complication.

Data management

To ensure data safety and security, all eligible patient data will be pseudoanonymised using a unique identification number. Data will be entered into the Research Electronic Data Capture (REDCap) web application (<https://redcap.umcg.nl>) or collected using paper forms (online supplemental appendices 1 and 2). Participating sites will



locally pseudoanonymise patient data by replacing personally identifiable information with pseudonyms before sharing. In addition, all documentation and recorded data must be retained for a minimum of 15 years after the study's completion. The transmission and storage of the information by REDCap is encrypted in accordance with institutional policies regarding subject privacy. Patient records will not be collected, used or disclosed for any other purposes than the study's purpose.

Statistical analysis

Descriptive statistics will be used for all variables collected. Categorical variables will be reported as counts (percentage). Normally distributed variables will be reported as the means and SD, and the skewed distributed variables will be expressed as median and the IQR. The χ^2 test or Fisher exact test will be used to compare categorical variables. Differences in continuous variables will be analysed by the Mann-Whitney U test (two groups) and Kruskal-Wallis test (multiple groups). Kaplan-Meier analysis will be applied for the analysis of primary patency and secondary patency as well as patient and graft survival. Statistical significance will be identified as a p value of <0.05. All data analyses will be conducted in IBM SPSS Statistics .26 software.

Patient and public involvement

Neither patients nor the public were involved in the design of this study.

ETHICS AND DISSEMINATION

This study will adhere to the local and national government laws, as well as the principles of the World Medical Association Declaration of Helsinki (Ethical Principles for Medical Research Involving Human Subjects). The study protocol in the Netherlands has been assessed by the University Medical Center Groningen's Institutional Review Board on 2 June 2023 (METc 2023/295), and it was determined that it does not fall under the Medical Research Involving Human Subjects Act (WMO). A data transfer agreement will be established to commence the study in compliance with the General Data Protection Regulation (EU) 2016/679. All of the participating sites will obtain institutional review board approval as required. The process of ethics approval across the participating centres (n=36) is as follows: 58% have received approval, 14% are under review, 6% have been submitted, and 22% are preparing for submission.

The results of this study will be presented at national and international scientific meetings and disseminated by publication in high-impact clinical journals through peer-reviewed manuscripts. In addition, the outcomes of this study will be presented to relevant patient groups, and the data will be shared with interested researchers. Furthermore, this study will be used to develop rational and feasible diagnostic and therapeutic approaches and,

ultimately, provide clinical decision-making models for HAC after paediatric LT.

The sites listed below are categorised by their consent protocols: opt-in with informed consent is practiced in the following countries, with the number of participating sites in parentheses: Australia (1), Brazil (2), China (1), Germany (3), India (4), Japan (1), New Zealand (1), Saudi Arabia (1), South Africa (1) and the USA (5). Opt-out with presumed consent is practiced in: Netherlands (1), Argentina (2), Austria (1), Canada (1), Czech Republic (1), France (1), Poland (1), Singapore (1), Spain (2), Sweden (1) and Switzerland (1). Italy (2) follows a hybrid approach, allowing for opt-in with informed consent and opt-out with presumed consent. The UK uses opt-in with required consent. The centre in China participating in this study has submitted an official document from the institute's relevant department. This document verifies that the transplanted livers are ethically sourced, coming from donors who have given their consent and are not considered part of a vulnerable group, including prisoners. The editors of the journal have reviewed relevant documentation.

Strengths and limitations

Strengths

This multicentre study will be the largest and first of its kind to investigate the incidence, current management practices and outcomes of paediatric patients with HAC after LT. Previous studies have only focused on the incidence and risk factors for early HAT and have failed to determine the optimal treatment and timing for paediatric patients with HAT.⁶ Moreover, most studies on HAC have been single-centre investigations, usually in adult or mixed populations; therefore, providing evidence regarding the management and outcomes of children is difficult. By including participating centres across the world, we aim to highlight the heterogeneity of care and, at the same time, also evaluate the effectiveness of different treatments.

This study will include at least 30 paediatric LT centres and is expected to contribute data for more than 400 patients. It will provide perspectives from a number of participating physicians. The international study setting will thus be able to address the aims and fill the evidence gaps on HAC after paediatric LT.

Numerous clinical studies have been performed, and no consensus has yet been reached regarding the current surgical and interventional (interventional radiology) management practices for paediatric patients who present with HAC, including the screening protocol and assessment criteria as well as the number of procedures, complication rate and anticoagulant therapy. Detailed and heterogeneous data on all these topics are expected. Finally, by advancing the development of a worldwide database, this study will lay out the foundation of the optimal management and treatment modalities of HAC for future prospective studies, clinical trials and implementation studies in the paediatric population.

Limitations

First, the retrospective nature of the study means that the data collected will be limited to what was documented in the medical records. A prospective study would be more suitable for accurate clinical and epidemiological research.

Second, because this is an observational study, it is important to note that the association does not indicate causation when interpreting the outcomes. Another potential challenge is the widespread use of different anticoagulation strategies and surgical techniques, which could hamper the analysis of the data. This diversity in approach may introduce variables that might affect the interpretation of the study's findings.

Third, there is a risk of missing data; however, this will be addressed by using a detailed case report form that includes the most important questions, as well as individualised contact with the research centres if uncertainties should occur.

Finally, the lack of a standardised definition of HAC may limit the consistency of the findings across centres. However, the diversity of interpretations can provide valuable insights and may encourage further exploration.

Implications for the future

The multicentre collaboration will generate data that can be used to improve clinical care and develop guidelines related to the diagnosis and treatment of HAC after paediatric LT. The findings of this study can also serve as a foundation for future prospective studies and contribute to the standardisation of screening and clinical decision-making for healthcare professionals treating patients with HAC.

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