

General Study Information

Title: RENOPORTAL & OTHER NON-ANATOMICAL ANASTOMOSES FOR PRIMARY ALLOGRAFT REVASCULARIZATION IN LIVER TRANSPLANT PATIENTS WITH EXTENSIVE PORTAL VEIN THROMBOSIS: AN INTERNATIONAL MULTICENTER OBSERVATIONAL STUDY"

Study Sponsors

- **Spanish Society of Liver Transplantation (Sociedad Española de Trasplante Hepático, SETH)**
- **European Liver and Intestine Transplant Association (ELITA)**
- **Hospital Clínic Barcelona**

Study Justification

Renoportal and other non-anatomical anastomoses may be performed in cases of complex portal thrombosis. These techniques appear to offer favorable results after transplantation, with high rates of anastomotic patency and resolution of symptoms of portal hypertension. To date, however, few cases have been reported in the medical literature, and it is possible that cases with suboptimal postoperative events and/or outcomes have not been adequately reported.

Bibliography

1. Hibi T, Nishida S, Levi DM, Selvaggi G, Tekin A, Fan J, et al. When and why portal vein thrombosis matters in liver transplantation: a critical audit of 174 cases. *Ann Surg* 2014 Apr;259(4):760-6.
2. D'Amico G, Hassan A, Diago UT, Hashmimoto K, Aucejo FN, Fujiki M, et al. Renoportal anastomosis in liver transplantation and its impact on patient outcomes: a systematic literature review. *Transpl Int* 2019 Feb;32(2):117-27.
3. Bhangui P, Lim C, Levesque E, Salloum C, Lahat E, Feray C, et al. Novel classification of non-malignant portal vein thrombosis: A guide to surgical decision-making during liver transplantation. *J Hepatol* 2019 Nov;71(5):1038-50.

Study Objective

Our objective is to create an international, multicenter cohort of patients that have undergone renoportal or other non-anatomical anastomoses for primary liver allograft revascularization for the purpose of analyzing indications, techniques, and outcomes in a manner that encourages reporting of all cases and reduces the risk of biased results due to underreporting.

Study Design

International, multicenter, retrospective, observational study.

Selection of Participants

Inclusion criteria: Adult recipients (≥ 18 years) of a first liver transplant in which renoportal anastomosis used as the primary form of allograft revascularization.

Exclusion criteria: Pediatric recipients; retransplants; and cases in which renoportal anastomosis was performed as a salvage technique following primary portal anastomotic failure.

Study Schedule

Patients will be included and study outcomes updated through early-to-mid 2021, depending on the rate of data entry. Following the completion of data entry, a first descriptive analysis of the results will be performed. Future studies based on the collected data will ideally emerge from this multicenter collaborative.

Study Policy and Legal Aspects

No center-specific data will be published, and all results will be reported anonymously.

Each center is free to publish its own data, regardless of its participation in RP4LT.

No data will be submitted or published without explicit authorization from each participating center.

Each center will be represented by its contributors, which ideally consist in one senior and one junior member.

Data will be collected via a secure, password-protected, and encrypted online data management system provided by the Hospital Clínic Barcelona. This platform uses a data entry management system that meets international standards for online databases, including complete anonymization of data.