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Study Identification

Unique Protocol ID:	4571
Brief Title:	Developing Prediction Models for Allograft Failure After Liver Transplantation (IMPROVEMENT)
Official Title:	International Multicenter Prospective, Non-competitive, Observational Study to Validate and Optimize Prediction Models of 90-day and 1-year Allograft Failure After Liver Transplantation
Secondary IDs:	

Study Status

Record Verification:	March 2022
Overall Status:	Not yet recruiting
Study Start:	April 1, 2022 [Anticipated]
Primary Completion:	December 1, 2023 [Anticipated]
Study Completion:	April 1, 2024 [Anticipated]

Sponsor/Collaborators

Sponsor:	Fondazione Policlinico Universitario Agostino Gemelli IRCCS
Responsible Party:	Principal Investigator Investigator: Prof. Alfonso Avolio [prof. alfonso avolio] Official Title: Professor Affiliation: Fondazione Policlinico Universitario Agostino Gemelli IRCCS
Collaborators:	University of California, Los Angeles University Hospital Padova Mayo Clinic Hospital Italiano de Buenos Aires Tokyo Women's Medical University Hospital Universitario La Paz First Affiliated Hospital, Sun Yat-Sen University University of Roma La Sapienza University of Massachusetts, Worcester The Cleveland Clinic Dr. Rela Institute & Medical Centre University of Toronto Universidade Federal do Paraná Royal Infirmary of Edinburgh Erasmus Medical Center

NOTE : "Dr. Rela Institute & Medical Centre" has been asserted to be a valid organization name by FPGemelliIRCCS.

Oversight

U.S. FDA-regulated Drug: No

U.S. FDA-regulated Device: No

U.S. FDA IND/IDE: No

Human Subjects Review: Board Status: Approved
Approval Number: 4571
Board Name: Ethics Committee
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Data Monitoring:

Study Description

Brief Summary: Prompt identification of allograft failure (AF) is highly desirable to address patients to liver retransplantation, in order to maximize results and preserve patients safety.

Recently, sophisticated kinetic models became available, offering the possibility to predict 90-day AF with unprecedented accuracy, by computing data from the first 10 days after liver transplant (LT).

The growing utilization of extended criteria and cardiac death donors stimulates the transplant community to further refine such predictive models and validate them on a larger scale population of patients across the nations.

This study aims to develop new algorithms for the timely prediction of AF at 90 and 365 days using a prospective international cohort from high-volume centers, to validate them on a large retrospective cohort, to identify the best time for retransplantation, to stratify the risk of AF according to the graft type (i.e. DBD, ECD, DCD, LD), to weigh the effect of risk-mitigation strategies, and to assess the correlation with post-LT morbidity and mortality.

Detailed Description: Background. During the last decade, the expansion of the donor pool by using extended criteria donors (ECD) grafts and those after cardiac death (DCD) have redrawn the attention around allograft failure (AF) due to ischemia-reperfusion injury after liver transplantation. The prompt diagnosis of AF is of paramount importance to define the indication for early re-transplantation. Moreover, the grafts from ECD and DCD not only may develop AF during the initial 90 days (early allograft failure, EAF) but also a slow-evolving type of failure, which presents up until 365 days.

The evaluation times and the modalities to promptly identify AF are still the object of research. At the same time, no consensus exists on the most accurate predictors of AF and on the possible mitigation strategies. In addition, ECD and DCD grafts are burdened by a higher incidence of ischemic cholangiopathy, that

typically develops after 6 to 12 months, which is also a cause of AF and need for retransplant.

Two scores, one developed in the United States at University of California Los Angeles (L-GrAFT) and one in Italy on a multicentric basis (EASE), allow the prediction of EAF with excellent C-statistics. Both were validated on multicentric external populations. L-GrAFT and EASE scores are calculated at day 10 after LT; a modification of the L-GrAFT score at day 7 has been developed and validated. Both scores are also proposed for quantifying the degree of graft recovery in translational studies. However, the prognostic role of pre-transplant histopathology of the graft as well as the detailed characterization of the dynamics that make retransplant sustainable or contraindicated and the possibilities to intervene to mitigate the graft-related risk remain unmet needs. Finally, the differences among phenotypic patterns of various transplant types (DBD, deceased donor grafts after cardiac death [DCD] and living donor grafts [LD]) have not been investigated, nor a large prospective study has been undertaken.

Rationale. Timely prediction of AF is pivotal to identify patients potentially benefiting from a rescue retransplant before severe complications develop. When massive cytolysis and clear signs of liver failure occur within the first 2-4 days after LT, the indication for a retransplant is clear, independently from the evidence of hepatic vessels thrombosis. Nevertheless, past 5 to 10 days after transplant, the decision whether or not to retransplant is often challenging. AF results from a complex interplay between donor, procurement-related, and recipient perioperative factors. All of them contribute to determine the severity and the capability to recover from the ischemia-reperfusion injury. However, several conditions and/or postoperative events may precipitate such capability (e.g., pre-operative cardiac ischemic damage, frailty-sarcopenia, graft rejection, drug toxicity, kidney failure, or severe infections or sepsis). Only a part of these factors have been studied. Additionally, although L-GrAFT and EASE scores can predict AF after 7 to 10 days, the trajectories of the graft towards recovery, successful or unsuccessful retransplantation and death without retransplant, have not been fully characterized yet. Despite the excellent accuracy and the efficacious discrimination ability, the existing studies have not elucidated the individual role of these events, nor competitive models have been developed in the perspective of retransplantation. Notably, literature is exclusively based on retrospective studies. Almost all these studies span an extended period of time, are often monocentric, do not consider the center volume effect, and are not balanced in the number of recruited patients in each center. Finally, only a small number of DCD grafts and ECD grafts managed by perfusion machines have been included in previous studies.

Study objectives:

- Primary to develop new algorithms for the timely prediction of Allograft Failure at 90 and 365 days using a comprehensive prospectively collected dataset based on the current clinical practice of high-volume centers.
- Secondary to validate the already existing predictive models and the newly developed algorithms on a retrospective cohort of patients from low to medium-volume transplant centers; to develop a novel time-based dynamic algorithm, with increasing accuracy from the 3rd to 7th post-operative day; to identify the best-time for re-transplant (after stratification according to the post-operative weeks, months, trimesters); to investigate differences in the incidence of Allograft Failure at 90 and 365 days according to DBD, DCD, LD donor grafts; to evaluate the effect of mitigation strategies on the precipitating factors of Allograft Failure at 90 and 365 days; to investigate the association of kinetic algorithms with development of post-LT complications (acute kidney injury, ischemic cholangiopathy, other complications); to identify risk factors for mortality that may contraindicate re-transplant.

Study design. Multicenter, international, non-competitive, observational two-cohort study. The two cohorts include a first cohort with prospective patient enrolment and a second cohort with retrospective enrolment.

A steering committee was constituted to design the study. Members were identified according to their experience on the topic and paying attention to their geographic area (Europe, Americas, Asia). The list of the Institution of all the steering committee members is included above. A draft of the preliminary study design and subsequent questionnaires on controversial issues were circulated among members.

No modification to the participating centers standard practice for the management of LT donors and recipients is required. The study has been structured according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.

Setting. The study will be conducted in 80 liver transplant centers from four continents (the final list of participating centers will be published as soon as all centers have confirmed and are ready to enroll).

Two distinct datasets will be created to collect data from the participating centers, depending on which of the two cohorts their patients belong to.

- Prospective cohort.
- Retrospective cohort. The study design includes two evaluation times (at 90 and 365 days after LT). Participants will be followed-up during their post-transplant hospital stay and at the liver transplant outpatient clinic after discharge from hospital. Readmissions to the hospital for any cause will be recorded.

Variables.

Main variable categories are:

- identification data (ID)
- donor characteristics data
- pre-operative data
- graft histology data
- intraoperative data
- post-operative data
- follow-up data

Data will be entered on the electronic Case Report Form (eCRF). The eCRF has been developed using the REDCap ver 10.0.21 software hosted at https://redcap-irccs.policlinicogemelli.it/, which includes ten forms:

1. ID data (LT progressive number, first 4 letter of the surname, LT date, LT type)
2. Donor data (standard parameters)
3. Biopsy data (central revision of uploaded scanned slides)
4. Pre-operative evaluation of the recipient (standard parameters)
5. Pre-operative quantification of Sarcopenia (central revision of uploaded CT scan)
6. Intra-operative data (surgical and anesthetics parameters)
7. Post-operative data (day 1-10)
8. Surgical complications data (paying attention to infections and contraindications to Re-Transplant)
9. End Point Indicators of graft function (CT scan, MR)
10. Outcome data at 90 and 365 days (ICU LoS, Hospital Los, Graft Survival, Causes of Graft Loss, Patient Survival) The eCRF allows easy calculation of scores including L-GrAFT and EASE scores.

The REDCAP software will automatically perform de-identification and encryption of the data.

The retrospective cohort dataset will include 75 variables, previously registered in the local-center data sources. They will be used to validate previously published kinetic algorithms.

Qualitative variables. Histology obtained during the back-table graft preparation, or alternatively at any time before graft implantation, will constitute a key point although not mandatory condition for the enrolment. The histology slides will be scanned at the local centers, de-identified and uploaded on the eCRF and centrally read for research purposes.Transplant candidates CT scan (DICOM files only) from the pre-listing work-up will be de-identified and uploaded on the eCRF and centrally read for research purposes. The incidence and grade of ischemic cholangiopathy will be measured by means of a cholangio-magnetic resonance (MR) at 10-12 months after LT (on-demand, based on clinical suspicion of ischemic cholangiopathy, e.g., higher than two-fold increase in baseline alkaline phosphatase levels). The DICOM files will be anonymized and uploaded on the eCRF and centrally read for research purposes.

Quantitative variables. Quantitative variables will be first explored by missing analysis at three levels: at a center level; at a country level; at continental level. Then, they will be assessed by descriptive analysis in the overall population and according to three main graft types. Donor characteristics, pre-operative, intraoperative, graft histology, and post-operative outcome-data will be assessed as potential predictors of the main outcome, i.e., allograft survival, as well as of patient survival at 90 and 365 days. The above-mentioned data will also be implemented in algorithms to chose the best time-window within which undergo re-transplant. Impact of donor age, graft percentage of macro-steatosis, Donor Warm Ischemia Time, Donor Asystolic Warm Ischemia Time, Recipient Warm Ischemia Time, Cold Ischemia Time, incidence of post-reperfusion syndrome, length of stay (LoS) in hospital and incidence of vascular thrombosis and of biliary complications (anastomotic and non-anastomotic) will be evaluated paying attention to the graft type.

Conditions

Conditions:	Liver Transplant Disorder
Keywords:	Liver transplantation Retransplantation Allograft failure End-stage liver disease Graft loss Patient survival Ischemic cholangiopathy

Study Design

Study Type:	Observational
Observational Study Model:	Cohort
Time Perspective:	Other
Biospecimen Retention:	None Retained
Biospecimen Description:	
Enrollment:	5000 [Anticipated]
Number of Groups/Cohorts:	2

Groups and Interventions

Groups/Cohorts	Interventions
Prospective Cohort Liver Transplant Recipients from High-volume centers (i.e., performing >= 65 LTs per year)	Procedure/Surgery: Liver Transplantation Individuals with end-stage liver disease will be subjected to liver transplantation from deceased or living donors
Retrospective Cohort Liver Transplant Recipients from Low-to-medium volume centers (i.e., performing <65 LTs per year) and High-volume centers	Procedure/Surgery: Liver Transplantation Individuals with end-stage liver disease will be subjected to liver transplantation from deceased or living donors

Outcome Measures

Primary Outcome Measure:

1. Allograft failure
   the irreversible loss of graft function leading to retransplantation or patient death

   [Time Frame: within 90 days after liver transplantation]
2. Allograft failure
   the irreversible loss of graft function leading to retransplantation or patient death

   [Time Frame: within 365 days after liver transplantation]

Secondary Outcome Measure:

3. Time to retransplantation
   The time lapsed from the first to the second liver transplant

   [Time Frame: 365 days]
4. Complications after liver transplantation
   The development of post-LT complications such as acute kidney injury, sepsis, respiratory failure, vascular thrombosis

   [Time Frame: 90 days]
5. Ischemic cholangiopathy
   The development of ischemia-related changes in the biliary ducts of the grafts that require active treatment (from antibiotics up to retransplantation)

   [Time Frame: 365 days]

Eligibility

Study Population: 5000 patients from 80 liver transplant centers (target size), divided in two cohorts: - Prospective: 2000 patients from 40 high-volume centers (performing ≥65 LT a year); 50 consecutive transplants; 365-day follow-up period. - Retrospective: 3000 patients from 40 medium-low volume centers (performing <65 LT a year); data collection of LTs performed between 31/12/2019 and 1/1/2017; 75 cases per center. High-volume centers will be allowed to enroll patients in the retrospective cohort too, enrolling a total of 125 transplants (50 prospective and 75 retrospective). Each cohort can accommodate >40 centers without altering the balanced study design (once the 40-center target has

been reached, each cohort can grow by a 20% extent above the target without altering the balance).

Sampling Method: Non-Probability Sample

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based: Yes
based on self-representation of gender identity

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

1. Adult recipients (≥18 years)
2. First transplant (retransplant cases should be enrolled if the first transplant is part of the study)
3. DBD grafts
4. DCD grafts (controlled and uncontrolled)
5. DBD and DCD grafts managed by perfusion machines
6. Living donor grafts (both left lobe and right lobe grafts) transplanted into adult recipients.
7. Split liver grafts (both left lobe and right lobe grafts) transplanted into adult recipients.

Exclusion Criteria:

1. Combined grafts (e.g., liver-kidney, liver-heart, liver-pancreas, multi-visceral grafts)
2. Domino grafts
3. Heterotopic grafts
4. Double grafts
5. Recipients undergoing liver transplants for cholangiocarcinoma and colorectal liver metastases

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IPDSharing

Plan to Share IPD: Undecided

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Links:

Available IPD/Information: