BIOGRAPHICAL SKETCH

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NAME: Jignesh K. Patel

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: Medical Director, Heart Transplant Program; Director, Heart Transplant Research

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Cambridge (Cambridge, England)	B.A.	1986	
University of Cambridge (Cambridge, England)	M.B.,B. Chir	1989	
Guy's Hospital (London, UK)		1993	Registrar, Pulmonary & Internal Medicine
The Cleveland Clinic Foundation (Cleveland, OH)		1995	Resident, Internal Medicine
UCLA Medical Center (Los Angeles, CA)		2000	Cardiology Fellow
University of California at Los Angeles (Los Angeles, CA)	PhD	2000	Physiology
UCLA School of Medicine (Los Angeles, CA)		2000	Chief Cardiology Fellow

A. Personal Statement

My research is primarily focused on clinical outcomes of patients after transplantation and cardiac amyloidosis. Our group's main goal is to identify therapies which abrogate the risk of allograft rejection and development of transplant vasculopathy, a chronic form of rejection, in heart transplant recipients. Specifically, we are embarking upon a number of clinical trials which will assess how best to monitor allograft rejection and assess the efficacy of novel agents in retarding the progression of transplant vasculopathy. We are also studying biologic agents which may minimize the risk of rejection in high-risk sensitized patients. We are conducting a number of clinical trials focused on novel therapies for transthyretin cardiac amyloidosis. I have experience in both basic science as a graduate (PhD) student and clinical research which allows me to be well suited to pursue this translational field. My doctoral thesis was focused on cellular mechanisms and cytokine involvement in vascular calcification. I have experience in writing research protocols, budgets and obtaining institutional review board approvals for clinical studies. My relevant research experience and strong physician-scientist background ensure that I will be a valued member of the team in this study.

B. Positions and Honors

Positions and Employment

1999 – 2000	Co-chair, Fellows-in-Training Section, California Chapter, American College of Cardiology
2000 – 2009	Consultant Cardiologist, Ahmanson-UCLA Cardiomyopathy Center
2003 – 2009	Associate Medical Director, UCLA Heart Transplant Program
2009 – present	Associate Clinical Professor, David Geffen School of Medicine at UCLA
2009 – present	Medical Director, Heart Transplant Program, Cedars-Sinai Heart Institute
2010 – present	Director, Heart Transplant Research, Cedars-Sinai Heart Institute
2016- present	Director, Cardiac Amyloidosis Program

Other Experience and Professional Memberships

1992	Royal College of Physicians of the United Kingdom
1994	American College of Physicians
1996	American College of Cardiology
1999	Scientific Council on Arteriosclerosis, Thrombosis and Vascular Biology of the American Heart Association
2000	International Society of Heart and Lung Transplantation
2001	American Society of Nuclear Cardiology
2010	Fellow of the American College of Cardiology
2016	Fellow of the Royal College of Physicians (FRCP)
2015	Abstract Selection Committee, International Society of Heart and Lung Transplantation
2015	Program Committee, International Society of Heart and Lung Transplantation (ISHLT)
2016	Vice-Chair, Heart Failure and Transplantation Council, ISHLT
2016	Thoracic Committee Member, American Society of Transplantation
2018	Chair, Heart Failure and Transplantation Council, ISHLT
2018	Associate Editor, American Journal of Transplantation
2018	Member, Heart Failure and Transplantation Council, American College of Cardiology

Journal Reviewer

Arteriosclerosis, Thrombosis and Vascular Biology
Circulation
Journal of Heart and Lung Transplantation
Journal of Transplantation
New England Journal of Medicine
American Journal of Transplantation
Clinical Transplantation
Journal of American College of Cardiology

C. Contributions to Science

1. A proportion of patients waitlisted for cardiac transplantation are deemed sensitized because they have circulating antibodies directed against human leukocyte antigen (HLA). These patients are more likely to have a positive prospective crossmatch and therefore have fewer acceptable donor hearts made available to them. This results in longer wait times and a higher rate while on the wait list compared with non-sensitized patients. Highly sensitized patients also show higher rates of mortality and higher incidences of rejection and cardiac allograft vasculopathy post-transplantation. I have conducted prospective and retrospective studies to show that there is both a survival benefit and an increase in freedom from complications for highly sensitized patients who receive treatment pre- and post-transplantation to reduce circulating antibodies against HLA. In a prospective single-center trial I demonstrated that treatment with bortezomib pre-transplantation decreased panel reactive antibodies (PRA) in patients refractory to treatment with intravenous immunoglobulin and rituximab thus increasing their chances of finding an acceptable donor. Sensitized patients are at increased risk of developing antibody mediated rejection (AMR). In an ongoing prospective clinical trial, I aim to show the effectiveness of eculizumab in decreasing the incidence of AMR.

a. Patel J, Everly M, Chang D, Kittleson M, Reed E, Kobashigawa J. Reduction of alloantibodies via proteosome inhibition in cardiac transplantation. J Heart Lung Transplant. 2011 Dec 31;30(12):1320-6.
b. Patel J, Reinsmoen N, Kittleson M, Dilibero D, Liou F, Chang DH, Hamilton M, Czer L, Esmailian F, Kobashigawa JA. Plasmapheresis and Bortezomib for Sensitized Patients Awaiting Heart Transplantation-Worth the Effort? J Heart Lung Transplant. 2015 Apr 1;34(4):S30-1.
c. Patel J. Cedars-Sinai Medical Center. The De-novo Use of Eculizumab in Presensitized Patients Receiving Cardiac Transplantation (DUET) In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2016 Nov 18]. Available from: http://clinicaltrials.gov/ct2/show/NCT02013037 NLM Identifier: NCT02013037

2. Solid organ transplantation owes much of its success to the effectiveness of immunosuppression. Allograft rejection and cardiac allograft vasculopathy (CAV) are common causes of mortality in heart transplant recipients. Triple therapy immunosuppression is important in preventing chronic rejection that leads to CAV. In a prospective randomized control trial our center was able to demonstrate that tacrolimus was comparable to cyclosporine (CyA) in terms of survival, freedom from rejection and freedom from CAV. Total cholesterol levels were comparable in both groups; however, triglyceride levels were lower in the tacrolimus group. Serum creatinine levels and levels of circulating anti-HLA antibodies were significantly lower in the tacrolimus group. Our findings were verified in subsequent prospective studies.

a. Kobashigawa JA, Patel J, Furukawa H, Moriguchi JD, Yeatman L, Takemoto S, Marquez A, Shaw J, Oeser BT, Subherwal S, Wu GW. Five-year results of a randomized, single-center study of tacrolimus vs microemulsion cyclosporine in heart transplant patients. J Heart Lung Transplant. 2006 Apr 30;25(4):434-9.

3. Cardiac allograft vasculopathy (CAV) is an aggressive form of coronary artery disease unique to heart transplant recipients. Once CAV afflicts the cardiac allograft, treatments are limited and usually involve re-transplanting the patient. Therefore, prevention remains the best option for combating CAV. In a prospective, randomized control trial our center showed the effectiveness of pravastatin in increasing the survival of, and reducing the incidence of CAV in heart transplant recipients. Ten-year freedom from death or re-transplantation was superior to the control group. Cholesterol levels were significantly lower in the treatment arm of the study to the point where 81% of the control group switched to using pravastatin during the 10-year follow-up period. Freedom from coronary artery disease at 10 years was 43% in the pravastatin group vs. 20% in the control group. Although many of the mortality and morbidity benefits from pravastatin were likely due to cholesterol lowering, we showed natural killer cell cytotoxicity was reduced in patients on pravastatin.

a. Kobashigawa JA, Moriguchi JD, Laks H, Wener L, Hage A, Hamilton MA, Cogert G, Marquez A, Vassilakis ME, Patel J, Yeatman L. Ten-year follow-up of a randomized trial of pravastatin in heart transplant patients. J Heart Lung Transplant. 2005 Nov 30;24(11):1736-40.

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

ALL IN/NIH 1U01AI136816-01 Madsen (PI) 05/01/2018-4/30/2020
Targeting Inflammation and Alloimmunity in Heart Transplant Recipients with Tocilizumab. The primary objective of the study is to compare the efficacy of standard of care triple maintenance immunosuppression plus tocilizumab treatment versus standard of care triple maintenance immunosuppression plus placebo on outcomes as defined by a composite 1 year post-transplant endpoint of a) detection of donor-specific antibodies (DSA), b) acute cellular rejection (ACR), c) antibody mediated rejection (AMR), d) hemodynamic compromise (HDC) rejection in absence of biopsy or histological rejection, e) death, and f) retransplantation.
Role: Center PI

Alexion Inc. Patel (PI) 2014-Present
The DUET Cardiac Trial - The De-novo Use of Eculizumab Alongside Conventional Maintenance Therapy in Presensitized Patients Receiving Cardiac Transplantation: An, Open-Label, Investigator-Initiated Pilot Trial. Investigational pilot trial to determine the safety and efficacy of the de-novo use of eculizumab to prevent symptomatic antibody (AMR≥1) and/or cellular mediated rejection (≥2 Grade 2R) in highly sensitized cardiac transplantation recipients (PRA>70%).

One Legacy Foundation/Baylor University Kransdorf (Site PI) 06/01/19-Present
Transplant of Redeemed Organs by Judicious Administration of New Direct Acting Antivirals for Hepatitis-C Heart Recipients (TROJAN-C). This prospective, multi-center, open-label clinical trial will utilize Hepatitis C virus (HCV) - Positive donors for heart transplantation in HCV-negative recipients.
Role: Co-Investigator

Pfizer, Inc. Patel (Site PI) 3/24/17-3/23/2020
ATTR- EXT - A Phase 3 Multicenter, Randomized, Double-Blind, Extension Study To Evaluate The Safety Of Daily Oral Dosing Of Tafamidis Meglumine (Pf-06291826) 20 Mg Or 80 Mg In Subjects Diagnosed With Transthyretin Cardiomyopathy (Ttr-Cm)

Genzyme Kobashigawa (PI) 07/01/2018 – 07/01/2021
A Pilot Randomized Study to Assess the Effect and Safety Profile of Thymoglobulin® in Primary Cardiac Transplant Recipients (ATG): A 12-month, single center, randomized, open-label study of efficacy comparing immediate treatment with and without Thymoglobulin® 1.5 mg/kg/d for 5 consecutive days in heart transplant recipients. The purpose of this study is to definitively establish Thymoglobulin's potential efficacy in preventing cardiac allograft vasculopathy.
Role: Co-Investigator

TransMedics Esmailian (PI) 09/11/2019 – 09/10/2022
OCS-CAR-121918 - Continued Access Protocol to collect additional evidence to evaluate the Safety and Effectiveness of The Portable Organ Care System (OCS™) Heart For Preserving and Assessing Expanded Criteria Donor Hearts for Transplantation (Heart EXPAND CAP
Role: Co-Investigator

Alnylam Pharmaceuticals Patel (site PI) 02/01/2020 – 01/31/2022
APOLLO-B - A Phase 3, Randomized, Double-blind, Placebo-controlled Multicenter Study to Evaluate the Efficacy and Safety of Patisiran in Patients with Transthyretin Amyloidosis with Cardiomyopathy (ATTR Amyloidosis with Cardiomyopathy)

Eidos Pharmaceuticals Patel (site PI) 05/21/2019 – 05/20/2022
Eidos AG10-301/ATTRIBUTE-CM - aprospective, randomized, multicenter, parallel-group study will evaluate the efficacy and safety of AG10 in symptomatic subjects compared to placebo, administered on a background of stable heart failure therapy

Donor Funded Marban (PI) 10/01/2019 – 09/30/2024
Cardiac Amyloidosis Registry Study ("CARS") - This multi-center effort will represent the largest collection of AL and TTR cardiac amyloidosis to date. (TBD) academic medical centers from the US will compile demographic, hemodynamic and organ-involvement data, as well as treatment strategies for AL and TTR amyloidosis.
Role: Co-Investigator

Completed Research Support

Alnylam Pharmaceuticals 3/13/15-3/12/18
A Study Examining the Prevalence of TTR Mutation in Subjects Suspected of Having Cardiac Amyloidosis. The goal of this project was to characterize the frequency of TTR mutations in subjects suspected of having cardiac amyloidosis.
Role: Center PI

Alnylam Pharmaceuticals 9/7/15-9/16/18
A Phase 3 Multicenter, Multinational, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of ALN-TTRSC in Patients with Transthyretin (TTR) Mediated Familial Amyloidotic Cardiomyopathy (FAC). The primary objective of the study was to determine the efficacy of ALN-TTRSC in patients with FAC.
Role: Center PI

Pfizer 12/1/14-1/31/19
A Multicenter, International, Phase 3, Double-Blind, Placebo-Controlled, Randomized Study to Evaluate the Efficacy, Safety, and Tolerability of Daily Oral Dosing of Tafamidis Meglumine 20 mg or 80 mg in Comparison to Placebo in Subjects Diagnosed with Transthyretin Cardiomyopathy (TTR-CM)
Role: Center PI