

Aav

Michael J. Castle

Adeno-Associated Virus (AAV) Vectors in Gene Therapy Kenneth I. Berns, Catherine Giraud, 2012-12-06 Human gene therapy holds great promise for the cure of many genetic diseases. In order to achieve such a cure there are two requirements. First, the affected gene must be cloned, its sequence determined and its regulation adequately characterized. Second, a suitable vector for the delivery of a good copy of the affected gene must be available. For a vector to be of use several attributes are highly desirable: these include ability to carry the intact gene (although this may be either the genomic or the cDNA form) in a stable form, ability to introduce the gene into the desired cell type, ability to express the introduced gene in an appropriately regulated manner for an extended period of time, and a lack of toxicity for the recipient. Also of concern is the frequency of cell transformation and, in some cases, the ability to introduce the gene into nondividing stem cells. Several animal viruses have been tested as potential vectors, but none has proven to have all the desired properties described above. For example, retroviruses are difficult to propagate in sufficient titers, do not integrate into nondividing cells, and are of concern because of their oncogenic properties in some hosts and because they integrate at many sites in the genome and, thus, are potentially insertional mutagens. Additionally, genes introduced by retroviral vectors are frequently expressed for relatively short periods of time. A second virus used as a vector in model systems has been adenovirus (Ad).

Immune responses to AAV vectors, from bench to bedside Federico Mingozzi, Hildegard Büning, Etiena Basner-Tschakarjan, Anne Galy, 2015-06-30 The recent wave of clinical studies demonstrating long-term therapeutic efficacy highlights the enormous potential of gene therapy as an approach to the treatment of inherited disorders and cancer. While in recent years lentiviral vectors have dominated the field of ex vivo gene therapy in man, adeno-associated virus (AAV) vectors have become the platform of choice for the in vivo gene delivery, both local and systemic. Despite the achievements in the clinic however, a number of hurdles remain to be overcome in gene therapy, these include availability of scalable vector production systems, potential issues associated with insertional mutagenesis, and concerns related to immunogenicity of gene therapeutics. For AAV vectors, clinical trials showed that immunity directed against the vector could either prevent transduction of a target tissue or limit the duration of therapeutic efficacy. Initial observations in the context of a gene therapy trial for hemophilia spurred over a decade efforts by gene therapists and immunologists to understand the mechanism and identify factors that contribute to AAV's immunogenicity, including the prevalence of B cell and T cell immunity to wild type AAV in humans and the interaction of AAV vectors with the innate and adaptive immune system. Despite a number of important contributions in particular in the more recent past, our knowledge on the immunology of gene transfer is still rudimentary; this is partly due to the fact that the basic understanding of the complex balance between tolerance and immunity to an antigen, key aspect of gene transfer with AAV, keeps evolving rapidly. However, continuing work towards a better definition of the interaction of viral vectors with the immune system has led to significant advances in the knowledge of the factors influencing the outcome of gene transfer, such as

the vector dose, the immune privilege of certain tissues, and the induction of tolerance to an antigen. A better understanding of the structure-function relationship of the viral capsid has boosted the development of novel immune-escape vector variants. In addition, novel immunomodulatory strategies were established to prevent or reduce anti-capsid immunity have been developed and are being tested in preclinical models and in clinical trials. Together, these advances are bringing us closer to the goal of achieving safe and sustained therapeutic gene transfer in humans. In this research topic, a collection of Original Research and Review Articles highlights critical aspects of the interaction between gene AAV vectors and the immune system, discussing how these interactions can be either detrimental or constitute an advantage, depending on the context of gene transfer, and providing tools and resources to better understand the issue of immunogenicity of AAV vectors in gene transfer.

AAV Gene Therapy: Immunology and Immunotherapeutics Jose Martinez-Navio, Nicole K. Paulk, Guangping Gao, 2022-02-09 Dr. Gao is the co-founder of Voyager Therapeutics, Adrenas Therapeutics and Aspa Therapeutics. His research laboratory receives financial support from sponsored research agreements with various companies including Merck and LuYe Pharma. The other Topic Editors declare no conflict of interest with regards to the Research Topic theme

AAV Virus and Vector Protocols Jeffrey S. Bartlett, 2005-07 reviews analysis of AAV genome integration in an in vitro model system; covers assessment of AAV entry into cells using a fluorescence approach; includes chapters on construction of recombinant AAV vector genomes, high-throughput analysis of recombinant AAV vector stocks, determination of AAV vector biodistribution, and the use of AAV vectors for gene transfer to the CNS.

Novel AAV Engineering Technology Martijn A. Cabanes Creus, 2019 Vectors based on Adeno-associated virus (AAV) are currently the most used gene transfer tools in the human gene therapy field. In order to overcome some of the intrinsic limitations of AAVs, lots of efforts have been put around AAV capsid engineering, with the ultimate goal of developing new recombinant serotypes with novel properties such as enhanced tropism for specific human cell types, increased manufacturability and decreased human seroreactivity. The work described in this thesis focus in an exhaustive revision of the process of new vector development. Firstly, we adapted new cloning strategies and bacterial selection on the AAV library construction field, allowing the generation of larger libraries, and reducing the time and effort needed for assembly. Secondly, we describe a new method based on codon optimization that when applied to AAV DNA-family shuffling overcomes the limitation encountered by phylogenetically distant serotypes to contribute on chimeric clones due to lack of DNA homology to other parental serotypes. This allowed to increase the complexity of the generated libraries. Thirdly, we generated and describe here a new high-throughput AAV vector selection platform to perform selection based on functional transduction (transgene expression). Briefly, we substituted the rep gene present on the AAV genome for a GFP reporter cassette under the control of a promoter of choice, and kept the cap library. This allows to transduce the cells of interest, FACS-sort the GFP positive cells and recover the capsid genes that encoded capsids that led to efficient functional transduction using PCR. Finally, we applied those three new AAV engineering technologies to develop novel capsids with improved tropism for primary human CD34+ cells, T-cells and hepatocytes.

Novel AAV Engineering Technology Martí Cabanes Creus, 2019

Adeno-associated Virus Vectors Michael J. Castle, 2019

Adeno-Associated Virus Richard O. Snyder, Philippe Moullier, 2011-10-28 Today, progress in rAAV-mediated gene transfer is so robust that long-term, efficient, and regulatable transgene expression is reproducibly achieved in large animal models. The complexity of gene transfer agents in the context of their clinical use requires investigators from a wide variety of backgrounds to have an understanding – or at least an appreciation of – the regulatory environment and constraints that affect vector design, manufacturing, pre-clinical testing, and clinical use, with an emphasis on patient protection. In *Adeno-Associated Virus: Methods and Protocols*, experts from the United States and Europe have contributed current knowledge of this multi-dimensional field relating to the biology of AAV, rAAV vector design, vector manufacturing and product testing, performance of rAAV vectors in major organs, rAAV-related immunological issues, design of animal and clinical studies, and clinical experience. Written in the successful *Methods in Molecular Biology*TM series format, chapters include introductions to their respective topics, lists of the necessary materials and reagents, step-by-step, readily reproducible protocols, and notes on troubleshooting and avoiding known pitfalls. Authoritative and accessible, *Adeno-Associated Virus: Methods and Protocols* provides a complete and comprehensive understanding of this multi-disciplinary and rapidly progressing field.

Small But Increasingly Mighty Stefanie Große, 2016

Muscle Gene Therapy Dongsheng Duan, 2009-11-26 Muscle disease represents an important health threat to the general population. There is essentially no cure. Gene therapy holds great promise to correct the genetic defects and eventually achieve full recovery in these diseases. Significant progresses have been made in the field of muscle gene therapy over the last few years. The development of novel gene delivery vectors has substantially enhanced specificity and efficiency of muscle gene delivery. The new knowledge on the immune response to viral vectors has added new insight in overcoming the immune obstacles. Most importantly, the field has finally moved from small experimental animal models to human patients. This book will bring together the leaders in the field of muscle gene transfer to provide an updated overview on the progress of muscle gene therapy. It will also highlight important clinical applications of muscle gene therapy.

Adeno-Associated Virus Richard O. Snyder, Philippe Moullier, 2016-08-23 Today, progress in rAAV-mediated gene transfer is so robust that long-term, efficient, and regulatable transgene expression is reproducibly achieved in large animal models. The complexity of gene transfer agents in the context of their clinical use requires investigators from a wide variety of backgrounds to have an understanding – or at least an appreciation of – the regulatory environment and constraints that affect vector design, manufacturing, pre-clinical testing, and clinical use, with an emphasis on patient protection. In *Adeno-Associated Virus: Methods and Protocols*, experts from the United States and Europe have contributed current knowledge of this multi-dimensional field relating to the biology of AAV, rAAV vector design, vector manufacturing and product testing, performance of rAAV vectors in

major organs, rAAV-related immunological issues, design of animal and clinical studies, and clinical experience. Written in the successful Methods in Molecular Biology™ series format, chapters include introductions to their respective topics, lists of the necessary materials and reagents, step-by-step, readily reproducible protocols, and notes on troubleshooting and avoiding known pitfalls. Authoritative and accessible, Adeno-Associated Virus: Methods and Protocols provides a complete and comprehensive understanding of this multi-disciplinary and rapidly progressing field.

The Parvoviruses Kenneth I. Berns, 2013-03-09 The Parvoviridae have been of increasing interest to researchers in the past decade. Their small size and simple structure have made them amenable to detailed physiochemical analysis, and from this work relatively detailed information has resulted that has significantly increased our understanding of the biology of these viruses. It has become clear that the Parvoviridae are of interest not only for their own sake, but also because their relative simplicity renders them useful probes in the study of the biology of host cells and of other DNA viruses with which they interact. The Dependovirus genus, for instance, contains the defective adeno-associated viruses (AAV), which require a coinfection with either an adenovirus or a herpesvirus for productive multiplication. Studies of AAV, therefore, necessarily impinge on our understanding of the control of macromolecular synthesis by the helper virus. Similarly AAV has been reported to inhibit the oncogenicity of both adenoviruses and herpesviruses and has been used as a probe of mechanism in these instances as well. Finally, AAV establishes latent infections in vivo and is the only mammalian DNA virus where a comparable model system has been established in cell culture. This system has allowed study of the mechanism of latent infection at the molecular level.

Interaction of Adeno-associated Virus (AAV) with the Transforming Genes of Adenovirus Jeffrey Marc Ostrove, 1980

Viral Vectors for Gene Therapy Fredric P. Manfredsson, Matthew J. Benskey, 2019 This volume discusses protocols, ranging from vector production to delivery methods, used to execute gene therapy applications. Chapters are divided into four parts, and cover topics such as design, construction, and application of transcription activation-like effectors; multi-modal production of adeno-associated virus; construction of oncolytic herpes simplex virus; AAV-mediated gene delivery to the mouse liver; and intrathecal delivery of gene therapeutics by direct lumbar puncture in mice. Written in the highly successful Methods in Molecular Biology series format, chapters include introductions to their respective topics, lists of the necessary materials and reagents, step-by-step, readily reproducible laboratory protocols, and tips on troubleshooting and avoiding known pitfalls. Comprehensive and authoritative, Viral Vectors for Gene Therapy: Methods and Protocols is a valuable resource for researchers, clinicians, and students looking to utilize viral vectors in gene therapy experiments.

Comprehensive Analysis of the Adeno-associated Virus (AAV) Transcriptome Based on Next Generation Sequencing Reveals New Insights Into AAV Biology Catrin Stutika, 2016

Anti-Neutrophil Cytoplasmic Antibody (ANCA) Associated Vasculitis Renato Alberto Sinico, Loïc Guillevin, 2019-09-13 This volume, written by well-known experts in the field, covers all aspects of Anti-

Neutrophil Cytoplasmic Antibody (ANCA) Associated Vasculitis (AAV). The expression refers to a group of diseases, characterized by destruction and inflammation of small vessels. The clinical signs vary and affect several organs, such as the kidney, lung, skin, nervous system and others. The opening chapters give some historical hints, explain the genetic basis of the disease and provide insights into the pathogenesis derived from recent experimental studies and guides the reader through classification and nomenclature. A large part of the book is then devoted to a detailed description of the specific related diseases and their clinical presentations, the disease course, and potential complications. The advice regarding treatment is based on the best currently available evidence in this constantly evolving area. The book is part of Springer's series Rare Diseases of the Immune System, which presents recently acquired knowledge on pathogenesis, diagnosis, and therapy with the aim of promoting a more holistic approach to these conditions. AAVs are systemic autoimmune diseases of unknown cause that affect small (to medium) sized blood vessels. They include granulomatosis with polyangiitis (formerly Wegener's granulomatosis), microscopic polyangiitis, and eosinophilic granulomatosis with polyangiitis (formerly Churg–Strauss syndrome). This volume will be an invaluable source of up-to-date information for all practitioners involved in the care of patients with these diseases.

Finnish Modern Design Marianne Aav, Nina Stritzler-Levine, 1998-01-01 This beautiful book examines the design achievements of Finland over the past seven decades, focusing on the central and decisive role played by Modernism. It discusses the work of such renowned architects and designers as Alvar Aalto and Kaj Franck, as well as of manufacturers, including Arabia and Marimekko.

Drug Development for Gene Therapy Yanmei Lu, Boris Gorovits, 2024-02-28 Drug Development for Gene Therapy Industry-centric perspective on translational and bioanalytical challenges and best practices for gene therapies Drug Development for Gene Therapy focuses on the translational and bioanalytical challenges and best practices for gene therapy modalities, presenting a significant body of data, including information related to safety and efficacy, necessary to advance through the development pipeline into clinical use. The text covers bioanalytical methods and platforms including patient screening assays, different PCR tests, enzyme activity assays, ELISpot, NGS, LC/MS, and immunoassays, with FDA and EMA guidelines on gene therapy safety and efficacy, along with companion diagnostics regulations from US and EU perspectives. The chapters offer an in-depth discussion of the basics and best practices for translational biomarkers, bioanalysis, and developing companion diagnostics / lab tests for gene therapies in the pharma and biopharma industries. To aid in reader comprehension, the text includes clinical examples of relevant therapies in related chapters. Some of the core topics covered include study design, immunogenicity, various bioanalytical methods and their applications, and global regulatory issues. Written by two highly qualified authors with significant experience in the field, Drug Development for Gene Therapy includes information on: Bioanalytical methods to detect pre-existing antibodies against adeno-associated viruses (AAV) capsids Detection of cellular immunity and humoral response to viral capsids and transgene proteins, and immunogenicity of gene therapy products Nonclinical and clinical study considerations and methods for

biodistribution and shedding Quantification of transgene protein expression and biochemical function, and substrate and distal pharmacodynamic biomarker measurements for gene therapy Detection and quantification of rAAV integration and off-target editing Current regulatory landscape for gene therapy product development and the role of biomarkers and general regulatory considerations for gene therapy companion diagnostics With comprehensive coverage of the subject, Drug Development for Gene Therapy is a must-have resource for researchers and developers in the areas of pharmaceuticals, biopharmaceuticals, and contract research organizations (CROs), along with professors, researchers, and advanced students in chemistry, biological, biomedical engineering, pharmaceuticals, and medical sciences.

AAV-plasmid DNA Simplifies Liver-directed in Vivo Gene Therapy Axel Doenecke,2013

Characterizing the Interaction of Adeno-associated Virus (AAV) with Factors of the Ubiquitin-proteasome System
Robin Wanjiru Njenga,2020*

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