Amyloidosis

WINTER 2023

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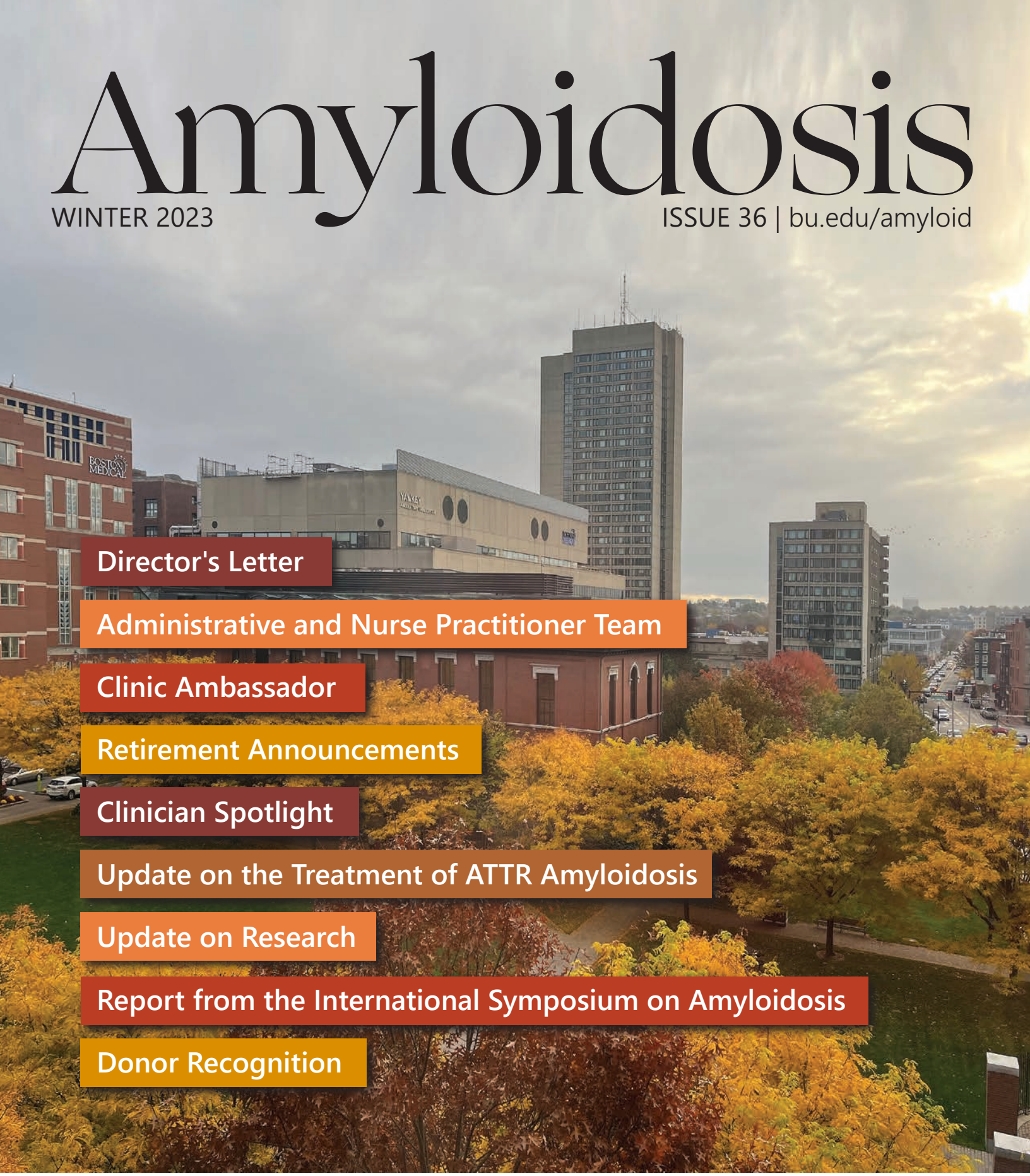


BOSTON MEDICAL CENTER

BU Chobanian & Avedisian School of Medicine
Amyloidosis Center

Director's Letter

Dear Friends,

Warmest thoughts and best wishes for 2023 from the Amyloidosis Center at Boston University Chobanian & Avedisian School of Medicine and Boston Medical Center. I hope you had a blessed holiday season.

It has been over six years since I accepted the position of the Director of the Amyloidosis Center from Dr. Martha Skinner. I remain humbled by the incredible engagement of our patients, friends and family of the Center. These have been an energizing and enriching last few years.

Our mission at the Amyloidosis Center ignites a journey of discovery and innovation. We value excellence at the heart of our work, and focus on initiatives for clinical and translational research. Our vision is to be a leader in transformational treatments and a center with purposeful impact.

The Amyloidosis Center continues to navigate from strength to greater strength, as it has done so effectively before. Building on previous leadership and guided by its strategic priorities, we are embracing a year of transformative milestones and tremendous potential. We are embarking on a new era with an ever-expanding therapeutic landscape for the various systemic amyloid disorders. Our Multidisciplinary Amyloid Clinical Program and Basic Laboratory Research Program continue to grow. Several new members have joined our high-performing and dedicated clinical team this year and we are pleased to welcome Dr. Andrew Staron (hematologist) and Dr. Ashish Verma (nephrologist).

Lawreen Connors, PhD, one of our most reliable colleagues and dependable friends, retired in July 2022. She led the Gerry Research Laboratory of the Center with exceptional energy, grace, and distinction for nearly 30 years. Her unwavering commitment, unparalleled spirit and scientific integrity is to be admired. We extend our heartfelt congratulations to Lawreen on her retirement.

The XVIIIth International Symposium on Amyloidosis was held in Heidelberg, Germany in September 2022. We firmly believe that collaboration with other amyloid teams will enhance discovery and cure for amyloid diseases. The report of this symposium is presented to you on page 8.

I hope you enjoy reading this report and learning more about this past year. Our hopes for 2023 are high; progress is only possible with your generous and steadfast support. Best wishes on behalf of the clinicians, administrative staff and researchers of the Amyloidosis Center. I take this opportunity to thank you for your support and friendship.

Sincerely,

Vaishali Sanchorawala

Vaishali Sanchorawala, MD
Professor of Medicine
Director, Amyloidosis Center

Administrative and Nurse Practitioner Team

Administrative Team

The administration team consists of the Program Manager, Alexis Doria, the Administrative Assistant, Ingrid Noriega, and the Temporary Assistant, Loren Watson. This team is responsible for scheduling patients, managing medical records, and making the patient experience as smooth as possible. They are dedicated to providing excellent service and are grateful for the opportunity to interact with our patients. Give us a call anytime and we will be happy to help!

Left to Right: *Loren Watson, Ingrid Noriega, Alexis Doria*

Nurse Practitioners – Beyond the Exam Room

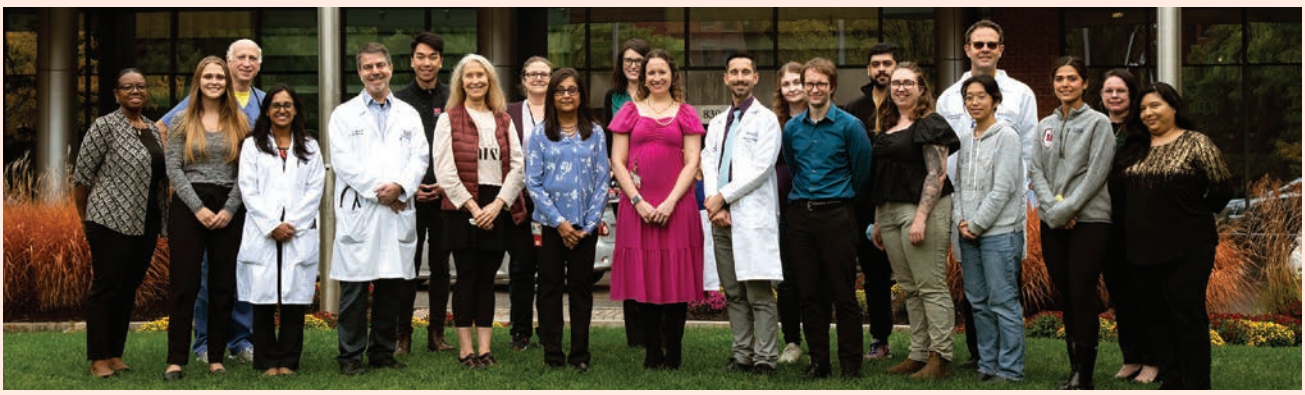
Left to Right: Tracy Joshi, Lisa Mendelson

Under the mentorship of Dr. Sanchorawala, both Tracy Joshi and Lisa Mendelson have made some amazing contributions to education this year. In addition to presenting "Cardiac Amyloidosis: Dos and Do Nots" to the new nurses at Boston Medical Center each year, Lisa also presented at the University of Calgary's fourth annual Amyloid Day, educating the nursing staff on symptom management of amyloidosis. Lisa was the lead author on "Understanding Amyloidosis: Unraveling the Complexities and Therapeutic Approaches for Oncology Nurses", which was featured in the Clinical Journal of Oncology Nursing's August edition, and focused on advocating for patients with her webinar "Empowering Patients: Navigating your care" through the Amyloidosis Research Consortium. Tracy was one of only two nurse practitioners selected to deliver an oral presentation at the 2022 International Symposium on Amyloidosis in Heidelberg, Germany, where she shared data on the largest cohort of patients with AA amyloidosis. Tracy is also a board member of Nursing Collaborative of the Amyloidosis Research Consortium, and is helping to improve patient and provider education materials for international use.

Clinic Ambassador

Reva Dolobowsky

We introduce our new clinic ambassador Reva Dolobowsky, who states..."I knew I wanted to be involved with Boston Medical Center's Amyloid Clinic ever since my husband's successful stem cell transplantation for AL Amyloidosis in 2009. We are so grateful to the team that has given him such excellent care! From my own visits as a family member in the clinic waiting room, I thought about how to make it a more comfortable, less stressful experience. So, I suggested that I could be a sort of patient liaison or ambassador. I spend one morning a week in the waiting room, visiting with patients and family members, keeping them company between appointments. I try to allay fears and make it a warm and welcoming place as we talk about their health issues, their travels, pets, grandchildren, and hobbies. Everyone has their own unique story about how they got to the Amyloid clinic, and I'm so fortunate to hear these stories!"



Retirement Announcements

Lawreen Connors, PhD

Lawreen Connors, PhD, one of our most reliable colleagues and dependable friends, retired in July 2022. Throughout the years, she has been a loyal member and irreplaceable part of the Amyloidosis Center.

Dr. Connors joined the Amyloidosis Center as a post-doctoral trainee in 1994 under the leadership of Dr. Martha Skinner. Dr. Connors obtained faculty appointments in the Departments of Biochemistry and Pathology in 1998 and 2009, respectively. She was inducted to Brown Professorship in 2018, a very proud moment for us all.

Left to Right: *Dr. Haili Cui, Dr. Lawreen Connors*

Dr. Connors focused her basic science research on uncovering the protein and genetic determinants that underlie the formation of amyloid. The early stages of her career featured structural analyses of amyloid-causing TTR variants, mainly those causing cardiac dysfunction. More recently, her studies have focused on wild-type TTR amyloidosis. She has received continuous support from the NIH and foundation grants, as well as industry-sponsored research agreements, and has authored more than 100 peer-reviewed scholarly articles and book chapters.

In 2009, Dr. Connors played a major role in the establishment of the Amyloid Pathology Diagnostic Testing Laboratory, a CAP-accredited and CLIA-certified facility that offers histologic and molecular testing for amyloid. Dr. Connors has mentored more than 20 master, doctoral, and postdoctoral students. She has served on multiple local, national and international committees.

She led the Gerry Amyloid Research Laboratory with exceptional energy, grace, and distinction for nearly 30 years. I know I speak for our Center in acknowledging the many contributions Lawreen has brought to the Center, the tremendous voice she has been on behalf of her laboratory members, and the spirit of fellowship and diplomacy she has embodied in her role.

As Lawreen takes on retirement, the Amyloidosis Center she leaves is a far stronger, richer, and more inclusive and welcoming for her efforts. We thank Lawreen for her many impactful contributions in advancing science and offer our heartfelt congratulations on her retirement.

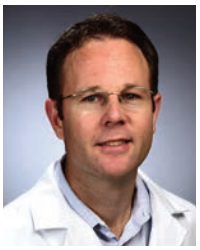
Dr. Haili Cui

After more than 10 years of outstanding service in the Boston University Amyloidosis Center Gerry Laboratory, Dr. Haili Cui retired this past June. She is greatly missed!

Dr. Cui served as the Amyloid Histopathology Laboratory Manager, overseeing all Congo red staining and immunohistochemical testing for amyloid proteins in our CAP-accredited and CLIA-certified laboratory. She worked closely with Dr. Carl O'Hara, a prominent amyloid pathologist and more recently with Dr. Eric Burks, in performing and evaluating 1000s of tissue samples for the definitive diagnosis and typing of amyloid disease. In addition, Dr. Cui collaborated on a variety of amyloid-related research projects with Drs. O'Hara, Burks and other amyloid investigators that led to a number of peer-reviewed publications. Her scholarly achievements also included participation at several International Society of Amyloidosis Symposia.

Dr. Cui's exceptional technical and analytical skills, extraordinary commitment, tireless dependability and commendable productivity made her a valued and essential member of our team. It is with great appreciation that we thank Dr. Cui for all her hard work and wish her all the best in retirement.

Clinician Spotlight



Dr. Eric Burks is a clinical associate professor of pathology and laboratory medicine at Boston University Chobanian and Avedisian School of Medicine. He is the medical director of hematopathology, immunohistochemistry, flow cytometry, amyloid center laboratory, and the hemoglobin diagnostic reference laboratory. He attended medical school at the University of New Mexico, his anatomic and clinical pathology residency at Penn State University followed by a surgical pathology fellowship at Brigham and Women's Hospital and hematopathology fellowship at Johns Hopkins University. Dr. Burks has been in practice as a surgical pathologist and hematopathologist since 2007. He is an expert in the diagnosis of amyloidosis, plasma cell neoplasms, and minimal residual disease testing by multiparametric flow cytometry. He is a key member of the Amyloidosis Center and leads diagnostics for patients with amyloidosis.

Dr. Burks states, "It is a great privilege to work together with such dedicated team of researchers and physicians to advance the diagnosis and management of patients with amyloidosis. The curiosity of my colleagues and the commitment to improving patient lives makes the work I do both exciting and meaningful!"

Dr. Gregory Grillone is the M. Stuart Strong and Charles W. Vaughan Professor and Chair of Otolaryngology-Head and Neck Surgery at Boston University Chobanian and Avedisian School of Medicine and Otolaryngologist-in-Chief at Boston Medical Center. He received his Medical Degree from the Icahn School of Medicine at Mount Sinai. He completed residency training in the Boston University-Tufts University Combined Otolaryngology Training Program. He then joined the full time faculty at Boston Medical Center and Boston University Chobanian and Avedisian School of Medicine where he has remained since.

Dr. Grillone's areas of clinical expertise include laryngology and surgery of the upper aerodigestive tract. He has special expertise in minimally invasive and endoscopic techniques to treat benign and malignant diseases of the pharynx, larynx and trachea including localized Amyloidosis.

Dr. Grillone has been a member of the multidisciplinary team at the Boston University Amyloidosis Center since the early 1990s. He states, "It has always been a privilege helping to care for our amyloid patients." We are so appreciative of all that Dr. Grillone does for the Center and our patients.

We welcome **Dr. Andrew Staron** into his new role as an expert hematologist on our clinical team. Dr. Staron has been affiliated with the Boston University Chobanian & Avedisian School of Medicine and the Boston Medical Center since 2015. He has a strong commitment to serving patients who come from diverse backgrounds, drawing upon his own upbringing in an immigrant family. Before his training in hematology and medical oncology, he completed a clinical and research fellowship at our Amyloidosis Center in 2018–2019 under the mentorship of the director, Dr. Sanchorawala.

He writes, "As I reflect back on my experiences at the Amyloidosis Center and think about my future, I consider how I might contribute the best of myself to the service of our patients and to advance the field of amyloidosis. I love working in a field where cutting-edge research makes its way from the bench to the bedside, providing patients hope and a second chance. I aspire to identify and apply new therapeutic strategies to change the course of this disease for patients".

In his role as an academic physician, Dr. Staron has been the lead author on several publications and given presentations at national and international meetings. For this work, he was a recipient of the American Society of Hematology Abstract Achievement Award in 2020 and 2021, and a recipient of the International Society of Amyloidosis Presidential Award in 2022.

Dr. Staron helps to oversee the clinical database at the Amyloidosis Center and is directly involved in clinical research projects utilizing this resource. He is an active member of the International Society of Amyloidosis and serves on the Membership Committee for this organization.

With his perpetual scientific curiosity and proclivity to develop longitudinal relationships with patients, we are thrilled to have Dr. Staron join our clinical team.

Dr. Ashish Verma is a clinician-investigator interested in chronic kidney disease (CKD) and paraproteinemia related kidney diseases. Dr. Verma's research projects include epidemiological investigations utilizing large databases and translational and patient-oriented research projects. Ongoing studies include: predictors of CKD progression using CRIC cohort, predictors of mortality in CKD patients using NHANES, physiology study examining the role of kidney function reserve and renal plasma flow in phenotyping chronic kidney disease and the role of intravitreal VEGF inhibitors in causing nephrotoxicity.

Dr. Verma states, "Amyloidosis is a rare disease that causes multiple organ dysfunction. This rare disease puts immense burden to affected patients and their families. It is a privilege and honor for me to take care of patients at the Amyloidosis Center. My aim is to help my patients by delivering the best clinical care and applying my research skills to create new knowledge inamyloidosis. I am thankful to my colleagues and my patients for the incredible opportunity to learn from them."

Update on the Treatment of ATTR Amyloidosis

Thirty years after the first liver transplant in a US patient with ATTR amyloid polyneuropathy, we began 2022 with 4 commercially available drugs (diflunisal, tafamidis, inotersen, patisiran) for ATTR amyloidosis. The prospects of new agents in the next several years, however, will eclipse this panel of therapeutics.

At present, 4 drugs are being tested in 6 phase III clinical trials to determine their effect on patients with ATTR amyloid polyneuropathy or cardiomyopathy. Two of the investigational drugs, vutrisiran and eplontersen, are new and improved versions of the TTR gene silencers patisiran and inotersen, respectively. These modifications make it possible to deliver the drugs by injection (no longer requiring intravenous infusion) using far less drug amounts on a less frequent basis (quarterly or monthly, depending on the drug). A new oral TTR tetramer stabilizer, AG10, is also in phase III testing.

New clinical trials focus on patients with two groups of ATTR patients: a) polyneuropathy or b) cardiomyopathy. The phase III polyneuropathy studies involve vutrisiran and eplontersen. Vutrisiran proved to be as effective as patisiran/OnPattro, and is recently FDA approved; preliminary data indicate eplontersen also benefits patients with ATTR amyloid polyneuropathy.

Phase III cardiomyopathy studies are examining the impact of patisiran, vutrisiran, eplontersen, and AG10 on a variety of measures of ATTR amyloid heart disease: the ability to walk distance, quality of life, survival, and heart-related hospitalizations. Preliminary data suggest patisiran alters the course of ATTR amyloid cardiomyopathy, although the impact of drug on many of the measures will require longer study treatment.

Finally, TTR gene editing studies are in early safety and tolerability testing, sponsored by Intellia Therapeutics. Preliminary data in a small number of study subjects provide proof of concept that scrambling the DNA code of the transthyretin gene can – to large degree -- prevent production of TTR. Ongoing studies aim to establish the optimal dose of drug, its safety, and the durability of the TTR suppressive effect. Ultimately phase III studies will need to demonstrate disease altering effect of the gene editing drug on ATTR amyloid polyneuropathy and/or cardiomyopathy.

Left to Right: Oltion Sina, Olivia Mueller, Charlotte Jean Michel, Dr. John Berk

Update on Research

By: Gareth Morgan, PhD and Tatiana Proakeva, MD, PhD

AL-Base

The most challenging aspect of AL amyloidosis is the uniqueness of the clonal light chain protein sequence in each patient that contributes to the diverse clinical presentation and disease course. Determination of the protein sequence from many individuals could help to identify light chains that carry an increased risk for amyloid formation and predict the pattern of organ and tissue involvement.

AL-Base, the repository of light chain nucleotide and protein sequences, was initially launched by the team of basic science researchers and bioinformatics experts from Boston University Amyloidosis Center in 2009. It is freely available to academic and industry scientists, as well as the public on the Boston University website at https://albase.bumc.bu.edu/aldb/.

Team from the Gerry Amyloid Research Laboratory

Recent developments in information technology and DNA sequencing techniques have vastly increased the amount of available genomic data over the past decade and dictated an urgent need for both infrastructure and content upgrades for AL-Base. The website and database software were upgraded to modern standards in 2021, with support from the Wildflower Foundation. Since then, newly published light chain sequences have been gathered from multiple recent studies in preparation for an AL-Base content update that is anticipated to go live in 2023.

To take advantage of these new resources, Amyloidosis Center researchers have developed computational methods to derive clonal light chain nucleotide sequences from gene expression data obtained from plasma cell dyscrasia associated disorders. Allison Nau, a new graduate from the Boston University Master's Program in Bioinformatics worked with Dr. Gareth Morgan, a Research Assistant Professor in the Amyloidosis Center, to carry out this project. Using Boston University's high performance computing cluster, this new algorithm was used to determine over seven hundred clonal light chain sequences associated with multiple myeloma, a plasma cell malignancy closely related to AL amyloidosis. This new cohort of sequences more than tripled the number of multiple myeloma-associated light chains previously reported in the AL-Base repository. The addition of these sequences to AL-Base will serve as a valuable control on studies carried out by Dr. Morgan and Dr. Prokaeva to identify sequence features that correlate with amyloid deposition in AL amyloidosis. This new method will accelerate the growth of AL-Base and provide an important resource for new approaches both at the Boston University Amyloidosis Center and other institutions involved in amyloid research around the world.

We are grateful to The Wildflower Foundation for supporting this update.

AB2M amyloidosis

In 2022, Dr. Tatiana Prokaeva, a Clinical Director of Amyloid Reference Laboratory, and Tracy Joshi, an Amyloidosis Center Nurse Practitioner, reported the results of study on a new unique P32L mutation in beta 2-microglobulin protein that caused a rare type of hereditary amyloidosis featuring dominant cardiac involvement in several members of a Portuguese family. This collaborative study conducted by the team of researchers from the Amyloidosis Center at Boston University, Amyloidosis Program at Brigham and Women's Hospital and Department of Health Sciences Research at Mayo Clinic was published in the *Amyloid Journal*.

Report from the International Symposium on Amyloidosis

By: Vaishali Sanchorawala, MD

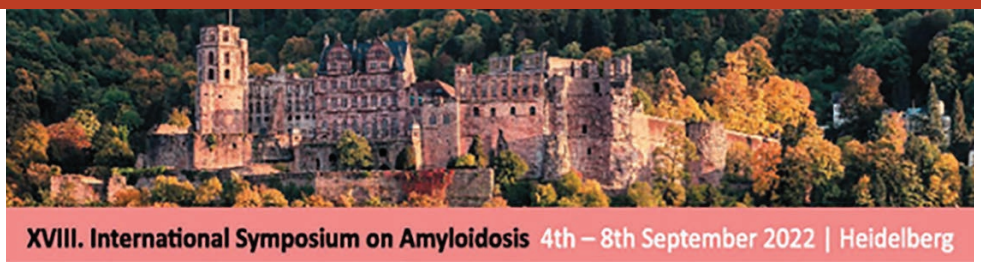
This gathering of leading experts in the field of amyloidosis is held biennially at different locations around the world. In September 2022, the four-day meeting was held in Heidelberg, Germany and comprised 25 lectures, 71 oral presentations, 309 poster presentations and 8 satellite symposia. There was notable growth in the number of participants and their countries of origin compared to prior years. Over 800 researchers from 50 countries attended the conference in-person, and nearly 300 more attended virtually. Participants gathered to share and discuss new research findings and to network for future collaboration. Our clinical and research team from the Boston University Amyloidosis Center was at the forefront, with ten members present for the scientific meeting in-person and two members participating virtually.

We had the privilege of presenting five oral presentations and fifteen posters at this year's meeting. The following scientific abstracts were some of the highlights from our team:

- *"Mapping and modelling the molecular mechanisms that drive amyloidogenic light chain-induced cardiotoxicity by unique transcriptional response"* presented by Dr. Camille Edwards
- *"Predictors of hematologic response and survival with stem cell transplantation in AL amyloidosis: a 25-year longitudinal study"* presented by Joshua Gustine (a fourth-year medical student at Boston University Chobanian & Avedisian School of Medicine)
- *"The prognostic importance of flow cytometry-based measurable residual disease (MRD) in patients with systemic light chain amyloidosis"* presented by Dr. Andrew Staron
- *"Natural history and risk stratification of AA amyloidosis based on a 40-year experience in the United States"* presented by Tracy Joshi, NP
- *"Potential sources of error in the identification and referral of amyloidosis to a tertiary center"* presented as a poster by Lisa Mendelson, NP
- "*Safety and efficacy of propylene glycol-free melphalan in patients with AL amyloidosis undergoing autologous stem cell transplantation: results of a phase II study"* presented as a poster by Dr. Michelle H. Lee (a hematology/oncology fellow at Boston Medical Center)
- *"Droxidopa for treatment of refractory orthostatic hypotension in patients with AL amyloidosis: a case series"* presented as a poster by Dr. Jorge Nicolas Ruiz Lopez (an internal medicine resident at Boston Medical Center)

Additionally, four of the basic science and clinical sessions at this year's meeting were chaired by members of our team. For example:

- Dr. Gareth Morgan delivered a superb state-of-the-art opening lecture as chair of the session on *"Basic research – New treatment targets and biomarkers."*
- Dr. Vaishali Sanchorawala passionately led an interactive session on *"Challenging cases"* and a panel discussion during the session on *"Beyond survival: Unmet medical needs in AL amyloidosis."*



The research endeavors from the Boston University Amyloidosis Center were well-received by the scientific community. In fact, we were granted both a presidential award (for an oral presentation on the prognostic role of MRD testing by Dr. Andrew Staron) and a poster prize (for a poster presentation on longitudinal testing for MRD by Dr. Andrew Staron) by the International Society of Amyloidosis. Furthermore, our research received a special mention in the meeting summary during the closing ceremony.

A number of other important amyloid-related topics were discussed at this year's meeting. These included:

- genetics underlying amyloidogenesis and the role of N-glycosylation
- evidence for cardiotoxicity of light chains in AL amyloidosis
- inhibition of fibril phagocytosis by the collagen that is associated with AL amyloidosis
- modulation of TTR proteolysis by SerpinA1
- development of a new kappa knock-in & seeding mouse model for AL amyloidosis
- artificial intelligence and machine learning for the detection of ATTR wild-type amyloidosis and prediction of light chain pathogenic potential
- serum neurofilament light chains as a potential biomarker of amyloid neuropathy
- role of imaging for the recognition of amyloidosis, characterization of disease severity, and monitoring of disease response
- potential future treatment modalities such as BCL-2 inhibitors, anti-BCMA therapies, BCMA-CART and CAEL-101 for AL amyloidosis; and novel anti-sense and stabilizer therapies for ATTR amyloidosis, along with a new antibody that may bind variant TTR

Knowledge sharing amongst world experts is important, as it creates opportunities to move the field of amyloidosis forward and, in turn, improve the quality of life of our patients with amyloid diseases. We truly appreciated the opportunity to be a part of the 2022 International Symposium on Amyloidosis.

Donor Recognition 2021-2022

The Amyloidosis Center at Boston University School of Medicine is pleased to recognize the generosity of its many donors whose support has assisted us in enhancing and continuing our progress in discovering a cure for amyloidosis. We thank our donors for their ongoing participation and commitment. This donor list recognizes individuals who have made gifts totaling $250 or more to the Amyloidosis Center between October 2021 and October 2022. We have made every effort to provide a complete and accurate list. We apologize in advance for any errors that may have been made. While space constraints prevent us from listing the names of donors of gifts under $250, we very sincerely appreciate the support of those many donors.

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BU Amyloidosis Center

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BOSTON MEDICAL CENTER

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