

THE SCIENCE OF HOPE

Salem VAMC Research



VA



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of Veterans Affairs



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AGENDA FOR RESEARCH WEEK 2019

Monday May 13	Tuesday May 14	Wednesday May 15	Thursday May 16	Friday May 17
<i>The Science of Hope: The Implementation of Our National Mission</i>	<i>The Science of Hope: It Takes a Village</i>	<i>The Science of Hope: It Takes a Village</i>	<i>The Science of Hope: Blazing the Clinical and Scientific Research Trail</i>	<i>The Science of Hope: Blazing the Clinical and Scientific Research Trail</i>
		Research Week on Living Local (WFXR)	POSTER SESSION <i>Location: 77-130D</i> 10:00 AM - 12:00 PM	GRAND ROUNDS <i>Location: 74-232</i> 7:45 AM - 8:45 AM
		Research Week Thank You Drive	HOSTED LUNCHEON <i>Location: 77-130D</i> 11:00 AM - 12:00 PM Mission BBQ	<i>Review of Current VA-funded Research</i>
LECTURE <i>Location: 75-209</i> 12:30 PM - 1:30 PM QUERI: <i>Accelerating Innovation, Implementation, and Sustainability in Real- World Practice</i> Amy Kilbourne, PhD MPH Director, VA Quality Enhancement Research Initiative (QUERI), DC	LECTURE/DISCUSSION <i>Location: 75-209</i> 12:00 PM - 1:30 PM <i>Pursuing Research with an External Collaborator</i> Francis Farrell, PhD Senior Director, Research & Development, Carilion Clinic		LECTURE <i>Location: 77-130D</i> 12:00 PM - 1:00 PM <i>Metformin: Is it a Cardiovascular Drug?</i> Gregory Schwartz, MD PhD Chief, Cardiology, Rocky Mountain Regional VA Medical Ctr, CO	Elias Lianos, MD PhD Novel Complement-targeted treatment strategies in Renal Disease Kris Ann Oursler, MD Strength Training & Endurance Exercise for Longevity - STEEL Alexander Krupnick, MD Work on Lung Transplantation & Lung Cancer Immunotherapy in the Krupnick Lab at UVA- SAMVAMC

WELCOME FROM THE ASSOCIATE CHIEF OF STAFF

Since the early 1920s, the VA Research and Development Program has been working to improve the lives of Veterans and all Americans through health care discovery and innovation. VA investigators have played key roles in developing devices and techniques that have helped revolutionize health care including the cardiac pacemaker, the CAT scan, Shingles vaccine, liver and kidney transplants, and much more. But, those contributions are not relegated to the history books.



Today, the VA serves as a leader in many areas of research, such as AIDS, mental health, genomics, heart disease, cancer, diabetes, infectious diseases, and spinal cord injury. VA conducts biomedical, rehabilitation, clinical, and health services research, as well as large, multi-center clinical trials, at more than 100 medical centers across the country. VA Research also foster dynamic collaborations with its university partners, other federal agencies, nonprofit organizations, and private industry—thus expanding the Program's impact on the health of Veterans and the Nation. Some of these partners are here today.

For over 30 years, researchers here at Salem VA Medical Center have been contributing to this grand history. Areas of current research at the Salem VA Medical Center include geriatric health and well-being, aging and neurological research, traumatic brain injury research, mental health, heart and kidney disease, cancer, diabetes, and infectious diseases. Our researchers represent a diverse range of specialties and perspectives, and yet work together as a research community intent on improving the lives of a diverse and ever-changing Veteran population. As part of our mission, we have worked to continually evolve and cultivate on-going, cutting-edge medical research and innovation to improve the lives of America's patriots. We are glad that you have joined us this week as we showcase some of the current research being conducted here at the Salem VA Medical Center.

Elias Lianos MD, PhD

Associate Chief of Staff, Research SAMVAMC



MONDAY - AMY KILBOURNE, PhD MPH

Director of QUERI - Quality Enhancement Research Initiative



Dr. Amy M. Kilbourne, PhD, MPH is Director of the VA Quality Enhancement Research Initiative (QUERI) and Professor of Psychiatry at the University of Michigan (UM) Medical School. With over 40 centers across the U.S., the mission of QUERI is to improve Veteran health by accelerating the implementation of research findings into real-world practice. Dr. Kilbourne's goal is to improve Veteran health through implementation science, i.e., the use of strategies to help providers scale up and spread effective practices in real-world treatment settings. She has led several national improvement initiatives a VA national population management program to provide outreach services for Veterans with serious mental illness (Re-Engage) and a community care implementation research roadmap. Dr. Kilbourne is the recipient of several awards including the Presidential Early Career Award for Scientists and Engineers (PECASE) and the Gerald L. Klerman Research Award from the Depression and Bipolar Support Alliance (DBSA). Dr. Kilbourne received her bachelors of arts at the University of California at Berkeley (double major in molecular biology and rhetoric), and her masters in epidemiology and PhD in health policy from the University of California Los Angeles.

TUESDAY - FRANCIS X. FARRELL, PhD

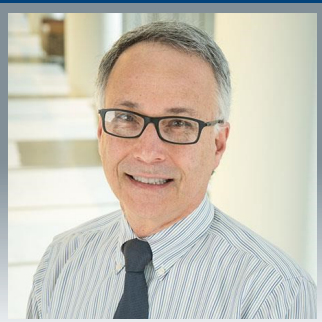
Senior Director of Research and Development, Carilion Clinic



Francis Farrell is the Senior Director of Research and Development at Carilion Clinic. Prior to joining Carilion Clinic, Francis spent the majority of his professional career in the pharmaceutical industry as a Drug Discovery /Early Development Scientist. He has experience in multiple therapeutic areas including hematology, immunology, metabolic diseases, stroke and tissue fibrosis. He was the lead discovery scientist on several therapeutic molecules for anemia and lung fibrosis. His team along with scientists from Affymax and The Scripps Research Institute were recipients of the Newcomb Cleveland Prize for their work on EMP1. Francis has published over 40+ peer reviewed publications and/or book chapters. He holds three issued patents. Francis received his PhD in biochemistry from Virginia Commonwealth University/Medical College of Virginia and did post-doctoral training at Burroughs-Wellcome.

THURSDAY - GREGORY G. SCHWARTZ, MD PhD

Professor of Medicine, University of Colorado School of Medicine and Chief, Cardiology Section, Rocky Mountain Regional VAMC, Aurora, Colorado



Gregory G. Schwartz, MD, PhD, is Professor of Medicine (Division of Cardiology) at the University of Colorado. He is also Chief of Cardiology at the Rocky Mountain Regional VA Medical Center in Aurora, Colorado (USA). Dr Schwartz graduated from Brown University in Providence, RI with a degree in Biomedical Engineering, and then received PhD and MD degrees from Duke University in Durham, NC. He completed residency in Internal Medicine at the University of Colorado and fellowship in Cardiology at the University of California San Francisco (UCSF), where he served on the faculty as Assistant and Associate Professor before assuming his present position.

Dr Schwartz' clinical research has focused on trials of lipid and metabolic interventions in coronary heart disease, including the placebo-controlled cardiovascular outcomes trials that established the efficacy of intensive statin treatment (MIRACL, 2001) and PCSK9 inhibition (ODYSSEY OUTCOMES, 2018) after acute coronary syndrome. Among current activities, Dr Schwartz is Chair of the VA Cooperative Study "VA-IMPACT" testing the cardiovascular efficacy of metformin in pre-diabetes. In basic research, Dr. Schwartz directs a swine physiology laboratory that investigates translational questions in myocardial energy metabolism and ischemic protection.

THE SCIENCE OF HOPE

Salem VAMC Research

***The Implementation of
Our National Mission***

POSTER SESSION - THURSDAY, MAY 16

ABSTRACTS

Amitabh Parashar, MD

COMPLETED STUDY

SAMVAMC RESEARCH

CMR utility in differentiating Low flow Low gradient AS from Moderate AS: How CMR helps detect LVOT area underestimation on TTE due to LVOT ellipticity

Transthoracic echocardiogram is the most widely used cardiac imaging modality for diagnosis and severity assessment of aortic stenosis. It is being increasingly recognized that LVOT diameter measurement error is a major source of incorrect aortic stenosis assessment.

25 subjects with continuity equation derived aortic valve area in severe range, with Doppler 2D data not convincing for severe aortic stenosis underwent Cardiac MRI to evaluate stroke volume to evaluate whether the discrepant data on TTE were due to Low flow Low Gradient normal LVEF AS (D3 ACC) or due to contribution of underestimation of LVOT area leading to decreased AVA on continuity equation. In this abstract, we present our data on LVOT measurements on TTE and LVOT dimensions on Cardiac MR: both AP and coronal diameters were obtained on CMR. 1.5 T Siemens Aera was used with ECG gating.

Echocardiographic derived LVOT area and CMR derived area varied due to different AP LVOT diameter measured by the two imaging modalities. Underestimation of LVOT dimension on TTE compared to Transesophageal echocardiography has been reported before as well. Incorporating LVOT dimension from coronal CMR images further accentuated the difference in LVOT area when, LVOT area from CMR data was compared to TTE. We noted a wide variation in ellipticity index on Cardiac MRI in individual patients. We found a weak correlation between the LVOT areas calculated using TTE and CMR in our cohort. Coefficient of correlation was calculated at 0.3557.

Underestimation of LVOT dimension on transthoracic echocardiogram should be suspected and taken into account while reconciling discrepant severity assessment of aortic stenosis between continuity derived AVA and assessment based on doppler velocity/gradients. Since there is wide variability in ellipticity index between individual patients; an accurate and reliable LVOT dimension from TTE may still leave scope for error. Cardiac MRI can help in such cases by giving us more accurate LVOT dimensions. In addition, AVA on CMR planimetry and flow data using PC sequences further helps assess AS severity. Potentially helps decrease need for invasive procedures and patient anxiety.

Nabil Jarmukli, MD

STUDY IN PROGRESS

SAMVAMC RESEARCH

A phase III randomised, double-blind trial to evaluate efficacy and safety of once daily empagliflozin 10 mg compared to placebo, in patients with chronic Heart Failure with reduced Ejection Fraction (HFrEF)

The trial is double-blind, multi-national, placebo-controlled, parallel group. Approximately 2850 will be randomized to treatment of oral empagliflozin 10mg daily versus placebo as add-on to standard of care treatment in patients with chronic heart failure with a reduced ejection fraction (LVEF $\leq 40\%$). Based on blinded assessment of the event rate of the primary endpoint, which is performed during recruitment before any interim unblinding, the number of patients randomized may be increased up to 4000.

Main criteria for inclusion: Patients with chronic HF diagnosed for at least 3 months before Visit 1 and currently in HF NYHA class II-IV; Chronic HF with reduced EF (HFrEF) defined as LVEF $\leq 40\%$ per local reading (obtained by echocardiography, radionuclide ventriculography, invasive angiography, MRI or CT; Reduced EF with elevated NT-proBNP; Stable and appropriate dose of medical therapy for HF (such as ACEi, ARB, β -blocker, oral diuretics, MRA, ARNI, ivabradine) consistent with prevailing CV guideline.

Heart failure is an important public health problem, and one of the leading causes of hospitalization in the Western countries. With the increasingly aging population and increasing incidence of obesity, the scope and cost to society associated with this condition will progressively rise. There is an unmet medical need in treatment of patients with HF, despite available therapies for HFrEF, outcomes remain suboptimal with increase rate of rehospitalization and high mortality rate. HF also significantly decreases health related quality of life (HRQOL) and pharmacological therapies have not shown consistent improvement in HRQOL.

Empagliflozin improves survival in patients with high cardiovascular risk by mechanisms which go beyond the blood glucose lowering effect. Expected benefit of empagliflozin such as BP reduction, weight loss, improvement in arterial stiffness, and hemodynamic changes, as well as CV benefits seen in patients with Type 2 DM is also speculated to be seen in HF patients without DM and in patients with chronic kidney disease stages 3 and 4. There are currently four patients enrolled in this study and recruitment continues.

Nabil Jarmukli, MD

STUDY IN PROGRESS

SAMVAMC RESEARCH

A phase III randomised, double-blind trial to evaluate efficacy and safety of once daily empagliflozin 10 mg compared to placebo, in patients with chronic Heart Failure with preserved Ejection Fraction (HFpEF)

The trial is event-driven and all randomized patients will remain in the trial until the defined number of adjudicated primary endpoint events has been reached. Randomization will be stratified with respect to geographical region, history of diabetes mellitus (DM), left ventricular ejection fraction (LVEF) and eGFR at screening. Estimated trial duration is 38 months with a recruitment period of approximately 18 months. The estimated length of the double-blind treatment will vary from approximately 20 to 38 months for each patient. The trial duration may be prolonged in case the number of patients and/or primary endpoint events is not reached within the planned timelines. The total number of randomized patients may be adapted based on assessment of the blinded event rate.

The trial is double-blind, multi-national, placebo-controlled, parallel group. Approximately 4126 will be randomized to treatment of oral empagliflozin 10mg daily versus placebo as add-on to standard of care treatment in patients with heart failure with a preserved ejection fraction (HFpEF). Based on blinded assessment of the event rate of the primary endpoint, which is performed during recruitment before any interim unblinding, the number of patients randomized may be increased up to 6000. There are currently two subjects enrolled in this study. Recruitment continues.

Kathleen Jean-Louis, PharmD Candidate*

COMPLETED STUDY

Juanetta Asare-Wassow, PharmD; Tammy Yu, PharmD Candidate*

SAMVAMC RESEARCH

Medication Utilization Evaluation of Fluoroquinolones Associated Hypoglycemia in non-diabetic Patient Admitted at Salem Veterans Affairs Medical Center Patients

The objective of this medication utilization evaluation (MUE) is to determine if Fluoroquinolone use during an inpatient stay has a significant impact on blood glucose levels in non-diabetic patients and if their restriction is necessary at the Salem VAMC. A retrospective chart review was performed using the Salem VA Medical system's electronic medical record. A data inquiry was requested and generated for Ciprofloxacin IV or PO, Levofloxacin IV or PO and Moxifloxacin IV or PO usage from January 1, 2017 to June 30th, 2018 at the Salem Veterans Affairs Medical Center. All inpatient non-diabetic patients receiving consecutive Fluoroquinolone therapy for at least 7 days were eligible for inclusion in the MUE.

Of the 55 patients that fell into the search criteria, 25 patients were randomly chosen for analyzation (45.5%). Of the 25 patients, 6 patients (24%) experienced hypoglycemia defined as any blood glucose level at or below 70 mg/dl (+/- 5 mmol/L). There were 13 patients that experience a drop in their blood glucose levels from baseline. Of the 13 patients (52%) that experienced a drop in their baseline, 11 patients (85%) had a decrease in blood glucose of over 20%. This MUE revealed that additional restrictions are warranted regarding Fluoroquinolone use in non-diabetic patients as there is a possibility for hypoglycemia.

* Appalachian College of Pharmacy and VCU College of Pharmacy respectively

Alexander Williams, MD

COMPLETED STUDY

Kathleen Glymph, DO; Ali Iranmanesh, MD

SAMVAMC IN PARTNERSHIP WITH VIRGINIA TECH CARILION

Prevalence of Opiate-induced Suppression of Corticotrophic Function in Veterans: A Retrospective Study at a Single V.A. Medical Center

Endogenous and exogenous opioids have been demonstrated to suppress the hypothalamic-pituitary-gonadal (HPG) and hypothalamic-pituitary-adrenal (HPA) axes. It is well established that opiate medications can cause secondary hypogonadism through inhibition of pulsatile gonadotropin releasing hormone (GnRH) and thus reducing luteinizing hormone (LH) release. While many studies have shown the inhibitory effects of both endogenous and exogenous opioids on the NPA axis the prevalence of this condition is unknown. We performed a retrospective study at a single, Veteran's Affairs Medical Center over a 10-year period (2006-2016) to investigate the correlation between opioid medication and adrenal insufficiency and the prevalence of this compared to other well-known causes of adrenal insufficiency. 138 patients were found to using serum cortisol less than 3.0 as the parameter. Out of these, 52 patients were undergoing overnight dexamethasone suppression tests to evaluate for hypercortisolism, and were excluded. Of the remaining 86 patients, 25 (29.07%) had received glucocorticoids, 14 (16.28%) had a normal afternoon or evening cortisol level, 9 (10.46%) had panhypopituitarism, 3 (3.49%) had primary adrenal insufficiency, 4 (4.65%) were taking megestrol acetate, 1 (1.16%) was suspected to be due to anti-retroviral medication, 4 (4.65%) were in the intensive care unit (ICU), and 24 (27.91%) were suspected to be related to opioid use. The remaining 2 (2.32%) patients had non-prescription opioid use but no repeat laboratory data was available. Of the 4 patients in the ICU, 3 were taking glucocorticoids and 1 was taking megestrol acetate. 10 of the 24 patients with low cortisol suspected to be secondary to opioid use also had gonadal hormones measured; of which 9 had either low FSH, LH or testosterone.

Alterations in Vascular Neural Networks Following Blast Traumatic Brain Injury

Traumatic brain injury (TBI) is a growing public health concern with a wide range of clinical and pathological consequences. Of particular interest to healthcare professionals serving military personnel and Veterans is the effects of blast injury on the brain. Disruption of vascular integrity and alterations in vessel reactivity have been reported as a result of blast TBI and can lead to damage of surrounding brain tissue which further contributes to long term neurological deficits. Researchers have demonstrated a dynamic and temporal response of the blood-brain barrier (BBB) opening and closing following blast exposure, however, the timeline and cellular mechanisms regulating these alterations are not fully understood.

To advance our understanding of vascular pathology at acute time points after injury, we characterized BBB integrity with immunohistochemical approaches 4 and 72 hours after blast exposure. We hypothesize that blast overpressure causes early changes in the vascular neural network (VNN) and impairs BBB functionality in the prefrontal cortex (PFC) and motor cortex (MC). Using an Advanced Blast Simulator located in the Center for Injury Biomechanics at Virginia Tech, rats were exposed to a single blast wave to induce primary blast-induced TBI (bTBI). Histological analysis was conducted to quantify endothelial barrier antigen (SMI-71) and aquaporin-4 (AQP4) which indicate endothelial proteins in areas with blood-brain barriers and water channel protein in the perivascular space, respectively.

The blast procedure introduced a positive pressure of 15.41 ± 0.51 psi (103kPa) and 16.51 ± 2.44 psi (110kPa) with a positive phase duration of 2.10 ± 0.06 ms and 1.79 ± 0.09 ms at 4 hours and 72 hours after blast exposure, respectively. Neuropathological changes were found at both acute time points following blast. Levels of AQP4 were significantly increased (p value = 0.04) in the MC but not PFC 4 hours after blast. We found no significant difference in the levels of SMI-71 in either brain region at this time point. At 72 hours after blast, levels of SMI-71 were significantly increased (p value = 0.03) in the MC and increased (p value = 0.08) in the PFC. We found no significant difference in AQP4 levels at this time point. These findings suggest early BBB alterations after blast exposure and will contribute to a better understanding of the dynamic temporal shifts in vascular integrity and function. Additional studies examining the VNN at later time points following injury will help elicit a broader understanding of the dynamic nature BBB structure and function. A comprehensive examination of the VNN will also provide necessary information regarding vascular dysfunction after bTBI and may lead to molecular targets for drug delivery which are currently lacking in the clinical arena.

Susan Murphy, PhD

STUDY IN PROGRESS

Pamela VandeVord, PhD; Michael Urban, PhD

SAMVAMC IN PARTNERSHIP WITH VIRGINIA TECH

Delayed Neuroinflammation following Repeated Blast Exposure

More than 25% of the Veterans returning from Operations Enduring and Iraqi Freedom, and New Dawn (OEF/OIF/OND) are suffering from symptoms of closed head injuries due to blast overpressure exposure. Reports suggest that improvised explosive devices (IEDs) are the main weapon of the current wars. To further complicate the injury, combat personnel can be exposed to multiple low-level blasts which could lead to the long term sequelae. The number of these individuals is increasing and poses a major long term challenge for the Department of Veteran Affairs. In order to determine molecular effects over time, an established rodent model of blast traumatic brain injury (TBI) was used and animals were monitored over a period of 6 months. Microglia are cells within the brain that function to balance the inflammatory response within the brain during injury and disease. We evaluated the chronic morphological change in microglia following single and repeated blast exposure.

Using an Advanced Blast Simulator located in the Center for Injury Biomechanics (CIB) at Virginia Tech, male rats were exposed to either a single or repeated (three times separated by one hour) blast wave to induce primary blast-induced TBI (bTBI). Sham animals were exposed to the same anesthesia and handling as their respective blast animals but not exposed to the blast wave. At one or six months, brains were collected. Histological analysis was conducted to quantify chronic microglia reactivity following injury. We characterized levels of IBA-1 in several regions of the brain (motor cortex (MC), prefrontal cortex (PFC), CA1 and CA2 of the hippocampus) with immunohistochemical approaches. Images were analyzed by calculating the area/cell using ImageJ software.

Results indicated that at one month after blast there was no significant change in IBA-1 area/cell. However, after 6 months the area/cell was significantly less in several areas of the brain. In the single blast group, it was significantly less in the MC, and CA1 and CA2 of the hippocampus compared to their sham. In the repeated blast group, IBA-1 was significantly reduced in the prefrontal cortex (PFC) and the MC when compared to its sham. We also compared the sham normalized ratios of the single and multiple blast exposures. These findings suggest a chronic morphologic changes in activated microglia. Changes are identified by cell ramification, having fewer and shorter processes. By comparing the area/cell we are analyzing the size and shape (i.e. the morphology) of the cell. In the images from the sham animals, the IBA-1 positive cells appear more numerous with more processes that are much longer and branched, whereas in the blast animals there appear to be fewer IBA-1 positive cells with fewer and truncated processes, hence calculating the area/cell is a sensible way to analyze IBA-1. These results indicate that there is a delayed neuroinflammatory response following repeated mTBI and merits further investigation into its involvement in secondary injury and involvement in the progressive debilitating symptoms of those who experience blast TBI and in discovering treatments to alleviate them.

Understanding Glial Dynamics in the Hippocampus following a Blast Induced Neurotrauma

There is a high risk for military personnel to suffer from traumatic brain injuries (TBI) and develop behavioral and cognitive disorders following a blast exposure. Major symptoms of TBI are associated with anxiety, impulsivity, memory issues, and attention deficits. The mechanism behind these symptoms have been associated with acute and chronic inflammation that are the result of blast-induced traumatic brain injury (bTBI), specifically in the hippocampus region of the brain. Astrocyte and microglia dynamics play a key role in initiating the inflammatory response after injury as microglia become activated undergoing morphological changes, and both activated microglia and reactive astrocytes release pro-inflammatory mediators after injury. This study aimed to better characterize the acute effects of microglia morphology and astrocyte reactivity in the hippocampus, specifically the dentate gyrus sub region, following a single blast overpressure in an in vivo model.

An established rodent model of blast TBI was used to produce a single incident pressure profile resembling a free field blast exposure in the Advanced Blast Simulator located at the Center for Injury Biomechanics at Virginia Tech. Sham controls underwent all the same procedures with the exception of the blast insult. At 72 hours following blast exposure, animals underwent a novel object recognition (NOR) assessment to measure behavioral and cognitive deficits, respectively. After 72 hours, brains were collected, embedded and processed for analysis. Immunohistochemistry was then performed on tissue samples to evaluate levels of Glial Fibrillary Acid Protein (GFAP; astrocyte reactivity) and ionized calcium-binding adaptor molecule 1 (IBA-1; microglia). The average total cell count per area for GFAP was calculated and the mean intensity, area per cell, and branches per cell, was calculated for IBA-1 for each image obtained for each animal. These values were then normalized to respective sham values.

The findings indicate that the blast introduced a positive pressure of 17psi (117kPa) with a positive phase duration of 2.5ms. Behavioral assessment determined trending changes in cognitive dysfunction in blast exposed animals. Neuropathological changes were found that depicted an acute inflammatory response in the brain such as increased levels of GFAP in blast animals indicating astrocyte reactivity. Levels of IBA-1 were evaluated leading to a more in depth analysis of microglia. Microglia skeleton analysis showed that there are diverse morphological changes that may indicate activation and phagocytic properties of microglia as an injury response. More specifically, endpoint voxels and branch length of microglia, showed decreases in blast animals in comparison to shams. Results showing decreased area of microglia somas in blast animals may also suggest increased microglia activation following injury. The results from this study demonstrate that there are trends that correlate the neuropathological changes seen in the hippocampus and the behavioral changes seen in blast exposed animals. More specifically, quantifying microglia morphology may provide insight for future detailed studies to differentiate between diverse microglia morphologies, further contributing to understanding the underlying mechanism contributing to the acute and chronic inflammatory response.

Kayla Spengler, PsyD

WORK IN PROGRESS

Lauren Hagemann, PhD; Katherine Luci, PsyD

SAMVAMC RESEARCH

Traumatic Brain Injury, Post-Traumatic Stress Disorder, and Pain Prevalence in a Sample of Rural Veterans Undergoing a Comprehensive Traumatic Brain Injury Evaluation

Recent discharge from a VA Community Living Center (CLC) has been shown to be a major risk factor for suicide in older Veterans. To assist Veterans with adjustment post-discharge, the Salem VAMC, along with other affiliates, has developed a care-transition tool called "Suicide Awareness for Veterans Exiting the CLC (SAVE-CLC)." SAVE-CLC was designed to provide Veterans with assistance in continued care as they adjust to residing back in the community. These calls include the completion of a mood screener and assessment of need for additional resources. A major factor in a Veteran's success following discharge surrounds the availability of supports. Oftentimes, this takes the form of an informal caregiver. In order to ensure caregivers are being offered the resources they need, an expansion of this project was developed to include the Zarit Burden Screener, a 4-item tool inquiring about caregiver stress. This screener, as well as additional caregiver specific questions, will be embedded in the existing CPRS template. All caregivers contacted will be mailed additional resources to help manage caregiver stress. Those who screen positive on the caregiver burden tool will be provided with additional options, such as extra follow up calls or specialized services from the geropsychology clinic. Since February 2019, 14 number of calls have been made to patients discharged of CLC, however few caregivers have been engaged (n=2). Potential barriers surrounding the lack of caregiver contact may include patient specific factors, such as declining requests to speak to caregivers or caregivers being unavailable at the time of call. Other considerations may be related to the lack of information relayed to caregivers upon discharge. Future directions will include the provision of training to our CLC discharge teams, to provide caregivers education about "next steps" so that they will anticipate follow up calls inquiring about current stressors or needs upon discharge.

Aliza Lee, DPM

WORK IN PROGRESS

SAMVAMC RESEARCH

Shortwave Diathermy therapy for failed conservative treatment of plantar fasciitis

Prospective case series of 25 consecutive patients with refractory plantar fasciitis whom have failed a conservative therapy modality for pain who will then be subsequently treated with shortwave diathermy. 3 months for treatment (90 days) with follow-up each month (for 3 months). 1, 2 and 3 months after by phone to measure pain free, reoccurrence, and/or, residual pain.

Shortwave diathermy can be used to treat selected medical conditions such as: relieving pain and increasing blood flow to tissues in the treatment area. Shortwave Diathermy therapy is used to interact or "program" cells to stimulate by delivering a radio band of 27.12 MHz. Cellular activity increases by almost 30% compared to non-treated control cells ($p < 0.001$).

Multi-national, multi-center, prospective randomized, double blinded, placebo-controlled trial to evaluate the efficacy of cyclic topical wound oxygen therapy in the treatment of chronic diabetic foot ulcers

The ADA estimates that Diabetes costs the USA \$327 billion annually with a large portion related to treating comorbidities such as Diabetic Foot Ulcers (DFU). Non-healing DFU lead to increased mortality, morbidity & health economic burden as well as decreased QOL. Our Multi-national, Multi-center, Prospective, Double Blinded, Placebo-Controlled Randomized Controlled Trial protocol was designed to explore the efficacy of a multi-modality cyclical Topical Wound Oxygen (TWO2) homecare therapy in healing refractory DFU of UT Grades 1 – 2, Stage A – D that had failed to heal with gold-Standard Of Care (SOC) alone.

A 220 patient Group Sequential Design was utilized for the study with 2 interim analyses (73 and 146 subjects) requiring a significance of $p < 0.022$ at each. All patients that consented and met a stringent eligibility criteria were first enrolled into a 2 week run-in of SOC that included Gold-Standard Offloading, sharp debridement and study provided advanced moist wound dressings. Only DFU not on a proven healing trajectory with Gold SOC alone (<30% wound area reduction) were randomized into the active phase of the study, where they were assigned (double blind) to either the active, or sham (placebo), TWO2 device treatment arms.

Subjects then administered the TWO2 therapy at home for 90 mins a day 5 days per week and visited the study site weekly for sharp debridement and wound assessment, including wound pictures, that were analyzed using automated CE marked wound software by a blinded central assessor. The primary endpoint of the study was ulcers achieving 100% healing at 12 weeks. Secondary endpoints included; wound reoccurrence up to 12 months, reduction in wound area, incidence of amputation, CWIS, EQ-5D-5L health assessments, and health economic analysis.

This robust study demonstrates that Cyclical Pressure TWO2 is significantly superior in healing recalcitrant DFU at 12 weeks compared to Gold-SOC alone. Furthermore, it resulted in even larger DFU not 100% healed at 12 weeks being on a trajectory to heal. It appears to be an easy to use homecare therapy with high patient compliance, and thus should be considered as a front line adjunctive treatment option for non-healing DFU.

Literature review and biomechanical findings in patients with bipartite medial cuneiforms

Bipartite medial cuneiforms are relatively rare but may play a significant role in biomechanical and gait abnormalities. It is believed that a bipartite medial cuneiform may alter the available range of motion due to its larger morphological variant, thus limiting the metatarsal plantarflexion needed to achieve adequate hallux dorsiflexion for normal gait. Radiographic and clinical assessment were performed on 2 patients who reported with foot pain along the first ray. Both patients had visible bipartite medial cuneiforms on MRI.

Using gait plate and Metascan™ analysis both were noted to have 4 measurements far beyond the expected range. Medial and lateral heel peak pressure, hallux peak pressure, and 1st metatarsal peak pressure was all noted to be increased. These measurements are believed to be increased due to the hindrance placed on the available ROM of the 1st ray by the increased size of the medial cuneiform. A larger patient population would be needed to fully understand this developmental anomaly.

The Effects of Incorporating Individual Evidence-Based Treatment in a Residential PTSD Program

The PTSD Residential Rehabilitation Treatment Program (PTSD-RRTP) has undergone significant programmatic and staffing changes during FY2016-FY2018, including shifting from an almost exclusively group therapy model to incorporating individual evidence-based practices (EBPs) for PTSD. Previously, the PTSD-RRTP program had provided group treatment using an Acceptance and Commitment Therapy (ACT) model. However, in response to veteran feedback, the program began incorporating individual treatment (predominantly Prolonged Exposure and Cognitive Processing Therapy, both EBPs). Since integrating individual therapy into programming, veterans have shown modest greater decreases in both PTSD and depression symptoms, based on measures collected at pre-treatment and post-treatment. This modest improvement in effectiveness has been maintained despite significant reductions in staffing. The findings strongly support continuing to implement individual therapy and maintaining adequate staffing ratios to allow for individual, as well as group programming. They also underscore the importance of considering veteran feedback in programmatic decision making.

Ripples of Recovery: Impact of Substance Use Treatment on Cognitive and Psychological Symptoms

Substance use disorders (SUDs) are associated with psychological symptoms, cognitive impairment, and impulsivity during periods of use and initial periods of abstinence. The primary purpose of the current study is to look at how to better identify these symptoms in individuals with substance use disorders and understand how they improve during treatment. Participants were recruited from a 28-day residential substance use treatment program. Measures included the Beck Depression Inventory-II (BDI-II), the Beck Anxiety Inventory (BAI), the Brief Addiction Monitor (BAM), the Montreal Cognitive Assessment (MoCA), and the Post-Traumatic Stress Disorder Checklist-5 (PCL-5). There were 200 participants who were primarily Caucasian and separated or divorced. On the BDI-II, the BAI, the PCL-5, and the MoCA pre- and post-treatment scores were significantly improved.

ACT for Older Adults: Transdiagnostic 20-Week Group Acceptance and Commitment Therapy

Depression, anxiety, and related mental health disorders are not a normal part of aging. However, old age is associated with an increase in certain chronic stressors such as age or illness related functional impairment and changing social roles. Failure to adequately adjust to these persistent stressors can subvert the normal trajectory of aging and trigger psychological distress. Unmanaged, this distress can develop into affective mental health disorders and lead to increased morbidity and all-cause mortality. Currently, the most commonly utilized psychosocial intervention, cognitive behavioral therapy (CBT), is based on the premise of cognitive restructuring to change thought patterns and decrease unrealistic negative cognitions. However, in the context of a chronic and severe stressor, these negative cognitions may in fact be realistic. Acceptance and Commitment Therapy is a promising alternative that emphasizes coming to terms with one's situation followed by committed action towards a more meaningful life.

This project aims to investigate an ACT intervention tailored to meet the needs of older adults with the overarching goal to enhance the quality of life and alleviate transdiagnostic distress. We hypothesize that ACT for Older Adults will increase quality of life and reduce symptom burden. The present study is a prospective pretest-posttest trial of group ACT for Older Adults in a transdiagnostic cohort of older Veterans. Patients experiencing psychological distress and symptoms of anxiety, depression, or related mental health disorders are recruited from around the Salem VAMC. The intervention takes place in two parts, each consisting of ten 1-hour weekly sessions. The first part focuses on building mindfulness and acceptance skills, and the second part emphasizes value-based living. Primary measures are the WHO Quality of Life-BREF (WHOQOL-BREF), Short Form Health Survey (SF-36), and process measures of ACT: Mindful Attention Awareness Scale (MAAS), Acceptance and Awareness Questionnaire (AAQ-II), and the Brief Resilience Scale (BRS). Symptom measures include the PHQ-9 for depression, PCL for PTSD, and GAD-7 for anxiety.

To date, we have developed a protocol to deliver ACT for Older Adults in a group setting. This protocol is based on prior work that shows older adults benefit from more experiential and concrete exercises that reduce the need for abstraction. More sessions were added to allow a slower pace relative to traditional ACT. We have enrolled our first group of 7 Veterans and therapy is on-going. We hope to begin a second group cohort this summer.

Intentional Self-Inflicted Injury: Lost Post-Discharge Mortality but High Recidivism Rates

Intentional self-inflicted injuries (ISI) present unique challenges in treatment and prevention. We hypothesized ISI would have higher in-hospital and post-discharge mortality than non-ISI trauma.

Adult patients evaluated 2008-2012 were identified in our trauma registry and matched with mortality data from the National Death Index. ISI were identified using E-Codes. Readmissions were identified and analyzed. ISI patients who died in-hospital were compared with those surviving to discharge. Univariate analysis was performed using non-parametric tests. Kaplan-Meier curves were plotted to compare mortality up to 5 years post-discharge between ISI and non-ISI patients.

8716 patient records were evaluated with 245 (2.8%) classified as ISI. 18 (7.8%) ISI patients had multiple admissions, compared to 352 (4.4%) non-ISI patients with readmissions ($p=0.0210$). In-hospital mortality was higher for ISI compared to non-ISI patients (18.7% vs 4.9%, $p<.0001$). Survival analysis demonstrated that ISI patients had significantly lower post-discharge mortality at multiple time points.

ISI trauma patients have high in-hospital mortality, but low post-discharge mortality. We attribute this to high lethality mechanisms but appropriate psychiatric treatment and rehabilitation. However, the high ISI readmission rate indicates further study of ISI follow-up is warranted. Better prevention strategies are needed to identify and intervene in patients at-risk for ISI.

Non-suicidal Self-Injury and Borderline Personality Features as Risk Factors for Suicidal Ideation among Male Veterans with Posttraumatic Stress Disorder

U.S. veterans face alarmingly high risk for suicidal ideation and behavior. Despite making up 7% of the population, they account for approximately 20% of all deaths by suicide. Veterans with posttraumatic stress disorder (PTSD) are four times more likely to report current suicidal ideation (SI) than are those without PTSD. Borderline personality features (BPF) are also associated with increased suicide risk; however, because most research has been conducted among civilian women, the impact of BPF among other populations remains unknown. Additionally, emerging research suggests that non-suicidal self-injury (NSSI) may be a unique risk factor for suicidal behavior. To examine the prevalence of BPF and NSSI and their relationship to suicidal ideation in the context of PTSD, we analyzed archival data from 728 male veterans. PTSD diagnosis was established by structured clinical interview. BPF were assessed by the Personality Assessment Inventory, and NSSI and SI were measured by self-report. Findings showed that NSSI and severe BPF were each relatively common in this sample of male veterans with PTSD (58.8% and 23.5% respectively) and each was associated with significantly increased odds of experiencing SI compared to PTSD alone (ORs ranged from 1.2 to 2.6). Furthermore, co-occurring PTSD, NSSI, and BPF (17% of the total sample) conveyed the highest odds of experiencing SI (ORs ranging from 2.13 to 5.68). The present findings provide new insight into the rates of NSSI and BPF among male veterans with PTSD and highlight the importance of these factors in suicide risk.

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Julian Lagoy, MD

COMPLETED STUDY

Adam Childers, PhD; Anita Kablinger, MD; Anjali Varma, MD

SAMVAMC IN PARTNERSHIP WITH VIRGINIA TECH CARILION

Attitudes of VA mental health professionals toward LGBTQ veterans

To study the attitudes of VA mental health providers using an anonymous 20-question survey and identify areas of bias, ease, and comfort levels and the need for provider education in relation to the LGBTQ patient population, an anonymous, voluntary 20 question survey based on the LGBT-DOCSS was emailed to psychologists and psychiatrists, including trainees in each of these disciplines, in the VA healthcare system the survey used included questions about demographic data, the providers' educational background, level of training, attitudes and challenges they have faced while caring for LGBTQ veterans. Several items on the survey were modified for the purpose of brevity and to assess attitudes of VA providers specifically.

This data set is composed of 118 responses from VA mental health professionals. Two primary areas were evaluated: did respondents believe a LGBTQ lifestyle as being immoral and do respondents feel prepared to professionally to care for LGBTQ patients? Just over 10% (12 of 118) of the respondents indicated that they believed an LGBTQ lifestyle is immoral but none of the demographic or professional descriptors, including race, religion, training, profession, age, and gender, were predictive for indicating this belief. Just under 39% (46 of 118, CI: .3898+- .0888) responded feeling unprepared in some capacity to care for the LGBTQ community. While none of the predictors were statistically significant, it was interesting to see that 45% (31 of 69) of females responded they felt unprepared while only 31% (15 of 49) of males said so (2-sample proportion, p-val = 0.1677). Further, 50% (10 of 20) of the under 30 age group felt unprepared which was higher than the any of age groups, most notably, 32% (16 of 49) of 30 to 39-year olds and 31% (8 of 26) of 40 to 49-year olds (Chi-Square test for independence, p-val = 0.2841). Among the professional groups, the psychiatry residents felt the most unprepared with 61% (16/26) indicating so (Chi-Square test for independence, p-val = 0.07169).

To our knowledge this is the first study examining mental health providers' attitudes towards the LGBTQ population in the VA healthcare system. The data show that VA mental health providers generally have positive views towards LGBTQ veterans. There were mixed responses about whether the current LGBTQ clinical training at the VA is adequate. Understanding what groups feel unprepared can help inform training decisions and necessitate education opportunities. As the VA strives towards providing equitable healthcare to the LGBTQ veterans, this pilot data may be used to develop future curricula for VA providers and can increase their awareness of their own attitudes and views towards the LGBTQ population.

Traumatic Brain Injury, Post-Traumatic Stress Disorder, and Pain Prevalence in a Sample of Rural Veterans Undergoing a Comprehensive Traumatic Brain Injury Evaluation

Previous literature (Cifu et al., 2013) has examined prevalence rates of the polytrauma clinical triad ((traumatic brain injury (TBI), post-traumatic stress disorder (PTSD), and pain) in Veterans serving in Operation Iraqi Freedom/Operation Enduring Freedom/Operation New Dawn. The current study sought to expand on Cifu's work by examining the polytrauma clinical triad in a sample of rural Veterans who screened positive on the TBI Clinical Reminder and who completed a Comprehensive TBI Evaluation in the Polytrauma Support Clinic.

Participants included 243 Veterans from the Salem VA from 2009-2016. Descriptive statistics were used to calculate prevalence rates of Veterans with isolated diagnoses (e.g., pain only) or a combination of diagnoses (e.g., PTSD and TBI). Further, self-report prevalence rates regarding areas of and functional implication of pain were also calculated.

The majority of the sample (87.2%) reported experiencing pain at the time of the evaluation while 64.2% were diagnosed with PTSD and 58.0% were diagnosed with TBI. In terms of multiple diagnoses, Veterans within the polytrauma triad group made up the largest portion of the sample (37.0%) followed by the combination of pain and PTSD (21.8%) and pain and TBI (14.4%). Within those experiencing pain, 84.1% reported at least mild functional impact with over half (58.2%) reporting moderate to severe impact. Head pain/headaches (66.7%) represented the largest area of pain in the sample followed by lower back pain (53.1%) and leg pain (49.3%).

Nearly 9 out of 10 Veterans included in this sample reported experiencing pain and within that subset of Veterans, the majority reported functional impact and pain related to the head, legs, and lower back. The results of this study suggest the importance of incorporating pain-related services and recommendations as a regular component of TBI evaluations with Veterans.

David O'Neil

Katherine Luci, PsyD; Lauren Hagemann, PhD

WORK IN PROGRESS

SAMVAMC IN PARTNERSHIP WITH VIRGINIA TECH CARILION

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Million Veteran Program (MVP): A Partnership with Veterans

The goal of the Million Veteran Program is to create a resource that allows for genetic and health research on diseases/conditions among Veterans with the ultimate goal of improving healthcare for all. The Million Veteran Program (MVP): A Partnership with Veterans is actively recruiting users of the VA Healthcare System who are willing to provide consent for collection of health information through passive and active methods. Methods include health record abstraction and collection of self-report questionnaires, stored in a VA MVP Central Research Database, and the collection of a blood sample, stored at a VA Central Biorepository. The recruitment goal of MVP is to enroll as many as one million Veterans nationwide. Participants will continue to be followed over time with linked health information.

MVP recruits a nationally representative sample of Veterans, ensuring inclusion of specific demographic and service era groups, including minority, female and younger Veterans through outreach. Veterans are recruited centrally using direct mailings and at the local site level utilizing numerous strategies for engaging walk-in recruitment such as informational brochures, posters, and material on kiosks. If amenable to participation, Veterans are asked to complete and return the MVP Baseline Survey which asks questions on topics such as demographics, family pedigree, personal and family medical history and healthcare utilization. If recruited centrally via mail, participants are mailed a letter following receipt of the completed survey indicating the time and date of the MVP visit. During the visit, participants undergo the consent process and donate a blood sample. By providing consent, participants grant permission to access their medical records, store the information in a VA Central Research Database and update the information on an ongoing basis. Following the MVP visit, a second questionnaire, the 'MVP Lifestyle Survey' is mailed to the participant. This optional questionnaire includes assessments relating to exercise and dietary habits, military and environmental exposures, and mental health. All blood specimens will be stored at a VA Central Biorepository until they are depleted or until no longer of scientific value, at which time they will be destroyed according to the biorepository procedures for disposal of human biological specimens.

Since the previous approval period, MVP has 60 sites with LSI application approval. In addition, several sites are planning to be inactivated as recruiting sites and replacement sites brought on. With the recruitment sites enrolling over the past year, a total of 717,808 Veterans enrolled as of November 29, 2018 with 94,516 of those having enrolled since the previous continuing review. The program has continued to modify recruitment materials and expansion of pilot activities and recruitment strategies to improve outreach.

In July 2015 four new studies were announced involving consortiums of VA researchers and university colleagues that will explore specific questions related to chronic illnesses common among Veterans. These projects were among the first to use the Million Veteran Program (MVP) data resource and serve as part of a 'beta test' for data access. There are currently five 'beta test' studies investigating the genomics of the following topics: cardiovascular disease risk factors, multi-substance use, cardiometabolic diseases, pharmacogenomics of kidney disease, and age-related macular degeneration. These studies have received VA Central IRB approval, Local R&D approval, and MVP data access approvals, and are in the process of conducting data analysis in their study specific study-marts.

Over the past year and a half, thirteen additional projects were approved as 'Gamma test' projects that will continue to help test our data access process and scientific computing infrastructure. The approved projects are studying topics including: genetic risk for suicide, predicting breast cancer risk for women Veterans, new computer algorithm to search our database, how gene variation relates to diseases, genetics of osteoarthritis, genetics of diabetes, cognitive impairment related to Alzheimer's Disease genes, genes related to Parkinson Disease, and genes related to tinnitus. These projects are currently going through the Central IRB review process. In addition, there are 4 BD-STEP projects approved focusing on the myeloma, lung cancer, genotype-guided Warfarin dosing algorithms, and pancreatic and liver cancer.



THE SCIENCE OF HOPE

Salem VAMC Research

***Blazing the Clinical and
Scientific Research Trail***

CURRENT RESEARCH AT SALEM VAMC

<i>Investigators</i>	<i>Title</i>
Dakshinamurty Gullapalli, MD Ali Iranmanesh, MD	Secondary Adrenal Insufficiency Following Prolonged Exposure to Exogenous Corticosteroids
Ali Iranmanesh, MD Mamta Sapra, MD Dakshin Gullapalli, MD	Correlation of Salivary Testosterone with Circulating Concentrations of Total, Free, and Bioavailable Testosterone and IGF-1 and Differential Role of Selective Macronutrients in Glucose Regulatory Mechanisms and Satiety in Healthy Men and Men with Concomitant Chronic Disorders
Ali Iranmanesh, MD Nabil Jarmukli, MD Amitabh Parashar, MD	Testosterone Replacement therapy for Assessment of long-term Vascular Events and efficacy ResponSE in hypogonadal men (TRAVERSE) Study
Soheir Boshra, MD Kris Ann Oursler, MD Brenda Davy, PhD RD	Resist Diabetes Qualitative Study
Tanvi Patil, PharmD Morgan Lebrecht, PharmD	A Retrospective Review of the Safety and Efficacy of Direct Oral Anticoagulants as Compared to Warfarin in a Morbidly Obese Veteran Population
Shikha Vasudeva, MD Stephanie Nagy-Agren, MD Kris Ann Oursler, MD, Aliza Lee, DPM	CSP #2001 Investigation of Rifampin to Reduce Pedal Amputations for Osteomyelitis in Diabetics (VA INTREPID)
Aliza Lee, DPM	A Multi-National, Multi-Center, Prospective, Randomized, Double-Blinded, Placebo-Controlled Trial to Evaluate the Efficacy of HyperBox Cyclical Topical Wound Oxygen Therapy (TWO2) in the Treatment of Chronic Diabetic Foot Ulcers
Aliza Lee, DPM	A Phase 3, Randomized, Double-blind, Parallel-group, Vehicle controlled, Multicenter Study of the Efficacy and Safety of Granexin Gel in the Treatment of Diabetic Foot Ulcer (GAIT 1)
Aliza Lee, DPM	Shortwave Diathermy Therapy for Failed Conservative Treatment of Plantar Fasciitis
Ali Iranmanesh, MD Amitabh Parashar, MD	SELECT - Semaglutide effects on heart disease and stroke in patients with overweight or obesity
Ali Iranmanesh, MD Nabil Jarmukli, MD, Thomas Martin, MD	Investigation of Metformin in Pre-Diabetes on Atherosclerotic Cardiovascular Outcomes (VA-IMPACT)
Ali Iranmanesh, MD Dakshin Gullapalli, MD	Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Assess Cardiovascular Outcomes Following Treatment with Ertugliflozin (MK-8835/PF-04971729) in Subjects with Type 2 Diabetes Mellitus and Established Vascular Disease
Amitabh Parashar, MD Nabil Jarmukli, MD Kristen Auckland, FNP Maribeth Capuno, ANP-CS Jacob Mathew, MD Jedediah McMunn, MD	Detection of Changes in Cardiac Biomarkers in Patients Undergoing Cardiovascular Stress Testing
Amitabh Parashar, MD Nabil Jarmukli, MD Kristen Auckland, FNP	A Double-Blind, Placebo-Controlled Study to Evaluate the Effects of Bexagliflozin on Hemoglobin A1c in Patients with Type 2 Diabetes and Increased Risk of Cardiovascular Adverse Events

<i>Investigators</i>	<i>Title</i>
Amitabh Parashar, MD Nabil Jarmukli, MD	A Global Study to Compare the Efficacy and Safety of Different Doses of Vericiguat with Placebo to Improve Physical Functioning in Activities of Daily Living in Patients with Heart Failure and Preserved Ejection Fraction (VITALITY-HFpEF)
Amitabh Parashar, MD Jedediah McMunn, MD	Usefulness of Novel and Standard Echocardiographic Criteria in Estimating Cardiac Filling Pressures
Amitabh Parashar, MD Jacob Mathew, MD Jedediah McMunn, MD	Evaluation of Single-Photon Emission Computed Tomography Parameters Predictive of Obstructive Coronary Artery Disease on Coronary Angiogram
Jacob Mathew, MD Amitabh Parashar, MD Umer Hayyat, MD	Validation of Dimensionless Index in Low-Flow Low Gradient Aortic Stenosis
Nabil Jarmukli, MD Amitabh Parashar, MD Kristen Auckland, NP-C Melanie Hinkle, PA-C Elizabeth Spangler Hall, PA-C	A Phase III, Randomised, Double-blind Trial to Evaluate Efficacy and Safety of Once Daily Empagliflozin 10 mg Compared to Placebo, in Patients with Chronic Heart Failure with Reduced Ejection Fraction (HFrEF)
Anuradha Sekhri, MD MPH	Sleep Apnea and Benzodiazepine Use – Correlations, Psychiatric Co-morbidities and Prescribing Practices
Anjali Varma, MD Mamta Sapra, MD Soroor Nemat, MD Greg Adams, PA	Prevalence and Comorbidities in Female Veterans with Sleep Apnea
Madalina Macrea, MD Kris Ann Oursler, MD	Evaluation of Exercise Capacity in Patients with Obstructive Sleep Apnea (OSA) and Chronic Obstructive Pulmonary Disease (COPD) [Overlap Syndrome]
Madalina Macrea, MD Kris Ann Oursler, MD	The Effect of Exercise on Systemic Inflammation in Veterans with COPD and OSA
Madalina Macrea, MD Kris Ann Oursler, MD	The Effect of Exercise on Biomarkers of Endothelial Function in Veterans with COPD and OSA
Cengiz Inal, MD Katie Kennedy, MD	Retrospective Analysis of Efficacy, Cost-effectiveness and Safety among Second-line Immunotherapy Options for Treatment of Advanced (Metastatic) Non-small Cell Lung Cancer
Cengiz Inal, MD	Clinical Outcome of Different Treatment Modalities in the Era of Targeted and Immunotherapy Therapies for Elderly Patients with Advanced Non-small Cell Lung Cancer
Alexander S. Krupnick, MD	High-Dose Targeted and Non-Toxic IL-2 Cytokine Therapy
Cengiz Inal, MD	Retrospective Analysis for Secondary Malignancies after Hematopoietic Cell Transplantation and Identifying Risk Factors among Veterans in USA
Edgar Castillo-D'Andreis, MD Cengiz Inal, MD Christopher Ripple, MD Ahmed Alkaram MD	A Randomized, Controlled Trial of ADV-TK + Valacyclovir Administered During Active Surveillance for Newly Diagnosed Prostate Cancer
Cengiz Inal, MD Edgar Castillo D'Andreis, MD Christopher Rippel, MD Ahmed Alkaram, MD	A Randomized Controlled Trial of Prostatak as Adjuvant to Up-Front Radiation Therapy for Localized Prostate Cancer

<i>Investigators</i>	<i>Title</i>
Ali Iranmanesh, MD Catherine Daniel, MD Dakshinamurthy Gullapalli, MD	CSP 594, Comparative Effectiveness in Gout: Allopurinol vs. Febuxostat
Ali Iranmanesh, MD Dakshin Gullapalli, MD Amitabh Parashar, MD	A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter, Event-Driven Phase III Study to Investigate the Efficacy and Safety of Finerenone, in addition to Standard of Care, on the Progression of Kidney Disease in Subjects with Type 2 Diabetes Mellitus and the Clinical Diagnosis of Diabetic Kidney Disease: (FIDELIO-DKD-16244)
Ali Iranmanesh, MD Nabil Jarmukli, MD Amitabh Parashar, MD	A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter, Event-Driven Phase III Study to Investigate the Efficacy and Safety of Finerenone on the Reduction of Cardiovascular Morbidity and Mortality in Subjects with Type 2 Diabetes Mellitus and the Clinical Diagnosis of Diabetic Kidney Disease in addition to the Standard of Care: (FIGARO-DKD-17530)
Devasmita Dev, MD Hima Bindu Yalamanchili, MD Sumeyye Calp-Inal, MD	Phase 3, Randomized, Open-Label, Active-Controlled Study Evaluating the Efficacy and Safety of Oral Vadadustat for the Correction of Anemia in Subjects with Non-Dialysis-Dependent Chronic Kidney Disease (NDD-CKD)(PRO2TECT-CORRECTION)
Devasmita Dev, MD Hima Bindu Yalamanchili, MD Sumeyye Calp-Inal, MD	A Phase 3, Randomized, Open-Label (sponsor-blind), Active-Controlled, Parallel-Group, Multi-Center, Event Driven Study in Dialysis Subjects with Anemia Associated with Chronic Kidney Disease to Evaluate the Safety and Efficacy of Daprodustat Compared to Recombinant Human Erythropoietin, Following a Switch from Erythropoietin-Stimulating Agents
Devasmita Dev, MD Hima Bindu Yalamanchili, MD Sumeyye Calp-Inal, MD	A Phase 3, Randomized, Open-Label (sponsor-blind), Active-Controlled, Parallel-Group, Multi-Center, Event Driven Study in Non-Dialysis Subjects with Anemia Associated with Chronic Kidney Disease to Evaluate the Safety and Efficacy of Daprodustat Compared to Darbepoetin Alfa
Devasmita Dev, MD Hima Bindu Yalamanchili, MD Sumeyye Calp-Inal, MD	Phase 3, Randomized, Open-Label, Active-Controlled Study Evaluating the Efficacy and Safety of Oral Vadadustat for the Maintenance Treatment of Anemia in Subjects with Non-Dialysis-Dependent Chronic Kidney Disease (NDD-CKD) (PRO2TECT-CONVERSION)
Devasmita Dev, MD Hima Bindu Yalamanchili, MD John Mihaltses, DO	Hepatitis B Vaccination in Chronic Kidney Disease, End-Stage Renal Disease, and Renal Transplants with Veterans Affairs Health System: Practice Patterns, Efficacy, and Cost Analysis
Devasmita Dev, MD Hima Bindu Yalamanchili, MD Sumeyye Calp-Inal, MD	A Phase 3, Intravenous Sodium Thiosulfate for Acute Calciphylaxis Treatment: A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Clinical Trial
Devasmita Dev, MD Hima Bindu Yalamanchili, MD Sumeyye Calp-Inal, MD Manavi Bhagwat Varun Kavuru John Robertson, PhD	Program to Increase Chronic Kidney Disease Education, Test Diet and Health OUTcomes (PICKED OUT)
Devasmita Dev, MD Hima Bindu Yalamanchili, MD John Mihaltses, DO Sumeyye Calp-Inal, MD	Efficacy of e-Kidney Clinic, an Internet Based Multimedia Patient Education Tool
Devasmita Dev, MD Hima Bindu Yalamanchili, MD Sumeyye Calp-Inal, MD	EMPA-KIDNEY: A multicentre international randomized parallel group double-blind placebo-controlled clinical trial of EMPAgliflozin once daily to assess cardio-renal outcomes in patients with chronic KIDNEY disease
Hima Bindu Yalamanchili, MD Shravani Reddy, MD Sumeyye Calp-Inal, MD Devasmita Dev, MD	Effect of Statins on Mortality, Major Adverse Cardiovascular Events (MACE) and End Stage Renal Disease (ESRD) in Chronic Kidney Disease Patients with Hypokalemia

<i>Investigators</i>	<i>Title</i>
Sumeyye Calp-Inal, MD Cengiz Inal, MD Devasmita Dev, MD Hima Bindu Yalamanchili, MD	A Retrospective Study of Patients with Plasma Cell Dyscrasias and Advanced Kidney Disease: Clinical Outcomes and Prognostic Factors for Kidney Transplantation
Elias Lianos, MD PhD	Novel Strategies in Minimizing Complement-mediated Kidney Injury
Devasmita Dev, MD Hima Bindu Yalamanchili, MD Deepa Lala, MD Sumeyye Calp-Inal, MD	MDA 2013-0039 Mino-Lok A Phase 3, Multi-Center, Randomized, Open-Label, Assessor-Blind Study to Evaluate the Efficacy and Safety of Mino-Lok Therapy (MLT) in Combination with Systemic Antibiotics in the Treatment of Catheter-Related or Central Line-Associated Bloodstream Infection
Devasmita Dev, MD Hima Bindu Yalamanchili, MD Sumeyye Calp-Inal, MD	A Phase 3, Multicenter, Double-Blind Study to Demonstrate Safety and Effectiveness of Neutrolin in Preventing Catheter-Related Infections (LOCK-IT-100)
Stephanie Nagy-Agren, MD Shikha Vasudeva, MD	A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Baloxavir Marboxil in Combination with Standard-of-Care Neuraminidase Inhibitor in Hospitalized Patients with Severe Influenza
Thomas Martin, MD Shikha Vasudeva, MD	A Phase 3, Placebo-Controlled, Randomized, Observer-Blinded Study to Evaluate the Efficacy, Safety and Tolerability of a Clostridium Difficile Vaccine in Adults 50 Years of Age and Older (Protocol B5091007) (CLOVER)
Stephanie Nagy-Agren, MD Brian Shenal, PhD Cirle Warren, MD	Gut-Brain Connection in Clostridium Difficile Infections in Elderly Veterans
Shikha Vasudeva, MD Michael Raczynski, MD Suzanne Stoneman, Kris Ann Oursler, MD	Prevalence of the O27 Ribotype in Southwest Virginia and the Implications for C difficile Treatment
Dana Holohan, PhD Candace Tomes, PsyD	Cost Effectiveness of Dialectical Behavior Therapy (DBT)
Brian Shenal, PhD	Mental Health in Rural Veterans with and without Traumatic Brain Injury
Brian Shenal, PhD Neena Cassell, PhD Abigail Feder, MA Ansley Corson, MA	Investigation of the Relationship between Patient Cognitive Functioning, Functional Status, and Anti-Dementia Medication Prescription
Anjali Varma, MD Mamta Sapra, MD	A Randomized, Double-blind, Placebo-controlled, Multicenter, Efficacy and Safety Study of Rapastinel for Rapid Treatment of Symptoms of Depression and Suicidality in Adult Patients with Major Depressive Disorder
Mark Detweiler, MD Brian Lutgens, MSW	Effect of Buspirone as a Treatment for Erectile Dysfunction Related to Sexual Side Effects of SSRIs, Other Antidepressants, Anxiety and Depressive Disorders
Mark Detweiler, MD Brian Lutgens, MSW	Is a Family History of Hypertension a High Risk Factor for Post-Traumatic Stress Disorders in Veterans?
Sarah VossHorrell, PhD Dana Holohan, PhD Bethany Morris, PhD	Predictors of Treatment Response Among Veterans with PTSD
Brooks King-Casas, PhD Pearl Chiu, PhD Stephen LaConte, PhD Steven Lash, PhD Emily Marston, PhD Katherine Cunningham, PhD Jacob Lee, MS	Efficacy and neural mediators of response to Trauma Management Therapy for PTSD

<i>Investigators</i>	<i>Title</i>
Brooks King-Casas, PhD	Neurobehavioral Assessment of Interpersonal Functioning in PTSD
Pamela VandeVord, PhD Michael Urban, PhD	Evaluating Causative Effects of Single/Multiple Neurotrauma on Neurodegeneration
Pamela VandeVord, PhD	Nanoparticles Mitigate Chronic Behavior and Neuropathology
Matthew Jameson, PhD Phil Lehman, PhD Steve Lash, PhD	Acceptance and Commitment Therapy for PTSD: Treatment Outcomes for an Inpatient ACT Program Posttraumatic Stress Disorder
Ali Iranmanesh, MD Alexander Williams, MD Kathleen Glymph, DO	Assessment of the Gonadotropic and Corticotropic Axes in Men with Opiate Dependence
Steven Lash, PhD Phil Lehman, PhD Jennifer Self, PhD Ashley Engels (Dibble), PhD	Ripples of Recovery: The Impact of Substance Use Treatment on Cognitive and Psychological Symptoms
Anjali Varma, MD Ilan Kerman, MD Ann Gregus, PhD Matthew Buczynski, PhD	Biomarkers of Chronic Pain
Bridgette Vest, NP Anjali Varma MD Sachin Vasudeva, MD	Efficacy of Battle Field Acupuncture (BFA) as an Adjunct to Buprenorphine/Naloxone Treatment in Veterans with Opioid Dependence and Chronic Pain
Bridgette Vest, NP Amela Jasarevic, FNP-BC Cecile Dietrich, NP	Substance Abuse Cessation for Veterans
Mark Detweiler, MD Rajdip Barman, MD	Prevalence of Late Onset Stress Symptomatology (LOSS) in Geriatric Combat Veterans and it's Relation with Dementia
Mamta Sapra, MD Anjali Varma, MD	A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy, Safety, and Tolerability of AVP-786 (Deudextromethorphan Hydrobromide [d6-DM]/Quinidine Sulfate [Q]) for the Treatment of Neurobehavioral Disinhibition including Aggression, Agitation, and Irritability in Patients with Traumatic Brain Injury (TBI)
Mamta Sapra, MD Anjali Varma, MD Katherine Luci, PhD	A Phase 3, Multi-center, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy, Safety, and Tolerability of AVP-786 (Deuterated [d6]- Dextromethorphan Hydrobromide [d6-DM]/ Quinidine Sulfate [Q]) for the Treatment of Agitation in Patients with Dementia of the Alzheimer's Type
Mamta Sapra, MD Anjali Varma, MD Katherine Luci, PhD	A Phase 3, Multicenter, Long-Term, Extension Study of the Safety and Efficacy of AVP-786 (Deuterated [d6] Dextromethorphan Hydrobromide [d6-DM]/quinidine sulfate [Q]) for the Treatment of Agitation in Patients with Dementia of the Alzheimer's Type
Mamta Sapra, MD	Relationship of Functional Independence and Perceived Quality of Life of Veteran Patients with Mild Cognitive Impairment (MCI) and Alzheimer's Dementia in Ambulatory Care Setting: a Cross-Sectional Study
Kris Ann Oursler, MD John Sorkin, MD, PhD	Long-term Improvements from Exercise (LIFE)
Katherine Luci, PhD Lauren Hagemann, PhD	ACT for Older Adults: Group Therapy for Fostering Psychological Flexibility in Older Adults (Sub-Study)
Katherine Luci, PhD Brian Shenal, PhD Heidi Maxwell, PsyD	Exploration of Dementia to a Memory Clinic that Result in Diagnosis of Major or Mild Neurocognitive Disorder

<i>Investigators</i>	<i>Title</i>
Mamta Sapra, MD Lauren Hageman, PhD	Caregiver Support Intervention and Biomarkers of Stress and Inflammation
Mamta Sapra, MD Lauren Hageman, PhD Katherine Luci, PhD	Practice of Acceptance, Awareness, and Compassion in Caregiving (PAACC): A Randomized Controlled Trial on Effectiveness of Mindfulness Based Caregiver Intervention
Ali Iranmanesh, MD Mamta Sapra, MD Maritza Carrillo, MD	Osteoporosis in Male Veterans
Kris Ann Oursler, MD Ali Iranmanesh, MD Madalina Macrea, MD Nabil Jarmukli, MD	Effect of Exercise Training on Inflammation and Function in HIV Infected Veterans
Jennifer Caldwell, PhD	Effects of an Intimate Partner Violence Training on Knowledge and Attitudes Toward Screening
Kris Ann Oursler, PhD	VA Million Veteran Program (MVP): A Partnership with Veterans
Neena Cassell, PhD Jessica Rusbatch, PsyD	Reliability of the Montreal Cognitive Assessment via Telehealth to Home
Shannon Munro, PhD NP Shikha Vasudeva, MD	Oral Hygiene and Prevention of Non-Ventilator Associated Hospital Acquired Pneumonia
Shannon Munro, PhD NP Mark Detweiler, MD Kris Ann Oursler, MD	Improving the Health of Veterans through Tai Chi
Amitabh Parashar, MD Nabil Jarmukli, MD Maribeth Capuno, ANP-CS	Hybrid Effectiveness —Implementation Study to Improve Clopidogrel Adherence

RESEARCH & DEVELOPMENT ADMINISTRATION



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Lynn Jernigan

Administrative Officer

Ms. Jernigan came to Salem VAMC in October 2018 from the North Florida/South Georgia Veterans Health System in Gainesville, FL where she began her tenure at VA in 2010 as an Administrative Officer (AO) for their HSR&D Center of Innovation on Disability and Rehabilitation Research. As AO, Ms. Jernigan supervises all R&D Administrative and Laboratory Staff. She also serves as officer of operations, budgets, human resources, etc. for the Research & Development Service (RDS). She has a passion for budgets and VA resource management which she puts to good use as she assists investigators throughout the grant process—from proposal to closure.



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Jessica O'Leary, PhD

Training & Education Coordinator

Dr. O'Leary joined the R&D Administrative Team at Salem VAMC in November 2018. She was brought on to serve in the new role of Training & Education Coordinator. Dr. O'Leary is primarily responsible for developing educational materials and implementing/delivering specialized training programs within the RDS. She also serves as a liaison for internal and external research staff members, providing support in areas of training, grant development, records management, and compliance. Utilizing her background in Extension Education, she also works with research teams to refine and disseminate their work to a more diverse audience base. Dr. O'Leary also acts as RDS liaison for research-based educational opportunities, including the undergraduate partnership with Roanoke College.



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Tracy Hicks

IRB Administrator

Ms. Hicks joined the staff at Salem VAMC in 2000. With an extensive set of experiences throughout the VA system, she puts her knowledge and skills to work, serving both as IRB Administrator and Human Research Protection Program (HRPP) Coordinator. Ms. Hicks coordinates all meetings for the protocol-required committees (Research & Development Committee, Institutional Review Board, and Safety Review Subcommittee). She currently acts on the role of lead for Records Management for open and closed protocols.



Donna.Arsura@va.gov
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Donna Arsura, RN, MA, CCRP, CIP

Health Science Specialist

Ms. Arsura has been with the Research and Development Service at Salem VAMC since September 2000. Pairing her prior experiences in the medical field with her keen grasp of protocol and procedures, Ms. Arsura serves as the RDS internal compliance and regulatory contact. In that role, she maintains all Standard Operating Procedures (SOPs) related to Research conducted here at SAMVAMC. She also serves as a key resource to the Research committees, investigators, and research staff.



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Carolyn Jones

Program Support Assistant

Ms. Jones has had an extensive and varied career within the VA Mid-Atlantic Region, serving in both Durham and Salem. Her most recent position is Program Support Assistant for RDS, which began in August 2015. This multi-dimensional background with the VA well prepared Ms. Jones for providing support to the ACOS and AO for Research in managing the human resource, payroll, and facility needs of the RDS. In addition to these tasks, Ms. Jones serves as the ADPAC for RDS, acting as the point of contact for all IT/Telecom related concerns. Ms. Jones is also the primary point of contact for all Travel, WOCs, and Outside Training Requests.



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Rachael Hartman

Administrative Support Assistant

Ms. Hartman joined Salem VAMC in September 2017, working with Salem Research Institute as a part-time Data Entry Clerk for several pharmaceutical studies. She was recently advanced to a full-time position, joining the Research and Development Service Administrative Staff as an Administrative Support Assistant. As an ASA, Ms. Hartman assists the AO in managing the operation, fiscal, and human resource needs of the Research & Development Service.

SALEM RESEARCH INSTITUTE, INC.



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Frances Hickman, RN

Executive Director

Fran Hickman boasts 45 years of nursing experience. She retired from the Salem VA with 35 years of service. Her most recent position there was as evening NOD (shift supervisor). Prior to that, she spent many years in the Medical and Surgical ICU's in various roles. Along with a PA, Ms. Hickman started the Advanced Cardiac Life Support program here at Salem many years ago and served as an Instructor until her retirement – also serving on numerous related committees. She joined SRI as Executive Director in July of 2015 relishing the opportunity to continue to serve Salem's Veteran population.

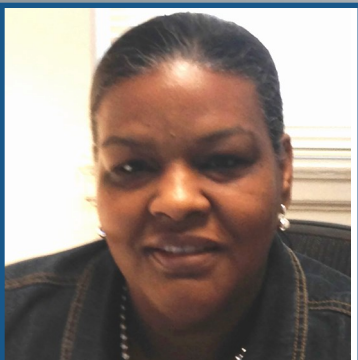


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Jenni Waters, MBA

Operations Manager

Jenni Waters joined the SRI Administrative Team in March 2018. She brought with her an extensive background in Business, Finance, and Accounting (a dual bachelors in Accounting and Finance as well as an MBA) which she is able to use on a daily basis in her role of Operations Manager for the non-profit. This role is quite multifaceted. Ms. Waters acts as Financial Officer while also assisting with pre- and post-grant management, resource utilization, and system workflow assessments.



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Donna Robinson

Administrative Assistant

Ms. Robinson Joined SRI in March 2016, bringing with her not only a strong knowledge of Business Administration and Human Resources, but also a working knowledge of non-profits. In addition to the work that she does here, Ms. Robinson also is the Director for the Cultural Arts for Excellence or CafeArts. This non-profit is a community center that supports an afterschool program for middle schoolers with an emphasis on the arts. Much of what she does for CafeArts translates into support SRI - such as fundraising, foundation grant-writing, and budgeting.

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