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TITLE:

Joint Global War on Terror (GWOT) Vascular Injury Study 2

PRINCIPAL INVESTIGATOR: MAJ Zachary Arthurs, MD

RECIPIENT: The Geneva Foundation

Tacoma, WA 98402

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14. ABSTRACT The objective of the proposed study is to initiate a large scale investigation of patient based outcomes following extremity vascular injury in the wars in Afghanistan and Iraq. This study proposes to link acute injury and clinical management information from the Joint Theater Trauma Registry (JTTR) to authentic patient-based outcomes years following injury. In this effort, the study aims to provide novel information on amputation and return to duty rates as well as to characterize the relationship between eventual quality of limb and psychological recovery or well-being.					
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1. INTRODUCTION:

The objective of the proposed study is to initiate a large scale investigation of patient based outcomes following extremity vascular injury in the wars in Afghanistan and Iraq. This study proposes to link acute injury and clinical management information from the Joint Theater Trauma Registry (JTTR) to authentic patient-based outcomes years following injury. In this effort, the study aims to provide novel information on amputation and return to duty rates as well as to characterize the relationship between eventual quality of limb and psychological recovery or well-being. Finally, this program aims to characterize and compare the physical and emotional burden in large cohorts of US service personnel having had successful limb salvage or amputation in the years following extremity vascular injury. An updated vascular study is needed to evaluate long-term outcomes and lifelong follow-up of the injured Service Member with vascular injury.

2. KEYWORDS: extremity vascular injury, extremity, vascular injury, vascular trauma, vascular injury management, survey, OIF, OEF, Iraq, Afghanistan, Iraq, deployment, training

3. ACCOMPLISHMENTS:

What were the major goals of the project?

- **Study Phase I (Acute and Mid-Term Data Collection):**
 - Several databases, including the JTTR, WISPR, PASBA, JPTA, AHLTA, DEERS, etc., will be searched to identify Service Members who incurred vascular injury in theater.
 - To augment data on acute injury characteristics and management strategies, a retrospective review of the medical records of those in the cohort will be performed.
- **Study Phase II (Patient Based Outcomes):**
 - Service Members identified via the database established in Phase I will be contacted to obtain status information to include the most recent date of vascular follow-up.
- **Study Phase III (Analysis):**
 - Information from Phase I and Phase II will be analyzed to provide comprehensive descriptive information on the patient cohort pertaining to demographics, injury information and management strategies.

What was accomplished under these goals?

Project was awarded on February 2013. Study Phase I of the project is underway and we have developed the surveillance program design and identified Service Members who incurred vascular injury. Two research nurse coordinators, one research fellow, one technical writer and one biostatistician have been hired in support of the award. The GWOT 2 Wartime Vascular Injury Study is an ongoing effort, therefore, the number injured continues to grow contingent upon additional potential subjects that are added to the database from yearly queries derived from the Department of Defense Trauma Registry (DoDTR). The Principal investigator, Col Todd Rasmussen, changed duty stations and he is now at Fort Detrick in Combat Casualty Care.

MAJ Zachary Arthurs was selected to be the incoming PI of this effort by Col Rasmussen and has taken leadership of the protocol. HRPO approval was obtained September 9, 2014.

Currently, 4,193 potential subjects have been identified with 3,725 records verified. Of those records, 1,574 did not meet criteria for inclusion, 1,418 were successfully contacted by the research staff and 686 consented to be included in the survey. From the consented subgroup, 518 health surveys and 380 vascular surveys have been returned. For the 2015 reporting year, 524 new patients were added to the database however, many are not meeting the inclusion criteria. 226 contact attempts were made for the new inclusions with 14 surveys returned. During IRB protocol review delays, the research staff reviewed all past records for quality control purposes and found updated contact information for 55 existing records. New attempts were made to contact the 55 patients with updated contact information resulting in 6 completed surveys. Also during this reporting period, Attempts were made to scan and enter in data from the Vietnam Vascular Registry. 167 records were manually scanned from the VVR files. On the regulatory side, Annual Continuing Review was completed and conditionally approved on 1 Jul 2015. After stipulations were met, full approval was received on 15 Jul 2015. After extended work, IRB approved Amendment 30 in July, 2015. A minor amendment 31, primarily for staffing changes, was approved in January, 2016. IRB Continuing Review approved 13JUL2016 and USAISR Protocol Audit Passed 22SEPT2016. After approval of a NCE in January 2016, RNCs continued to work on adding records to the database. Of note during this reporting period is the large drop off in new potential subjects. The team continued to screen incoming potential subjects, contact, consent and include in the study with some limited success. There are currently 4,193 records in the database. As of 31JAN2017, 22 additional records have been verified in the GWOT database to bring the total to 3795. Of those, 14 records did not meet criteria bring the excluded total to 1615. 7 new extremity injuries were identified for a new total of 1,585. 5 new subjects were contacted successfully but unfortunately, there was no increase in survey consents which remains at 689. 525 SF36 surveys have been completed with 380 vascular surveys completed. As the year progressed, efforts turned to database quality control in preparation for study draw down. In November of 2016, staff began investigating the possibility of preserving the GWOT2 data after study conclusion to allow access by future researchers. The GWOT2 study team met with Joint Trauma System (JTS) representatives who were willing to investigate transfer of GWOT2 data to JTS for future management and preservation. After budget analysis, it was determined that adequate funds remained to apply for a final NCE. The NCE would allow enough time for the database transfer to JTS custody and any final protocol modifications deemed necessary. Application for NCE was submitted in January 2017. GWOT2 was approved for a no cost extension of the project until 30JUN, 2017 in January of 2017. Currently, the GWOT2 team is working with JTS on database transfer and are on target for on time completion.

What opportunities for training and professional development has the project provided?

The GWOT2 Project continues to provide professional development opportunities for its research staff as well new research opportunities for surgical residents focusing on vascular research at SAMMC/USAISR.

How were the results disseminated to communities of interest?

We aimed at disseminating and promoting the GWOT 2 Wartime Vascular Injury Study to the research community through national civilian and military academic conferences/or meetings. Details are included in Section 6 of report. Additionally, once we complete manuscripts, these will be submitted to peer-reviewed journals for publishing.

What do you plan to do during the next reporting period to accomplish the goals?

In the final phase, we plan on completing any remaining database quality control until such time arrives that we can transfer the completed database over to the JTS for final custody. In the interim, we will continue to work closely with JTS to arrange the transfer while securing any needed protocol changes and approvals.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Vascular injury represents a common cause of morbidity and mortality in not only wartime but also the civilian trauma sector in the US. Historically advances in the management of civilian disease and injury have resulted from wartime experience in the areas of burn care, resuscitation, infectious diseases and vascular surgery. What is learned from the mid and long-term follow up provided by this study will undoubtedly impact the management of age-related vascular disease in the United States. Additionally the management of vascular injury in the civilian setting stands to benefit from the activities of this study. Given the minimal published data on host national vascular injuries, any information in this arena would be of potential benefit to developing proven management strategies. Lastly understanding of vascular injury including limb ischemia and reperfusion is relevant to other vascular distributions including the coronary and cerebrovascular circulations which are also prone to ischemic insult.

For the first time, this study proposes a mixed methods approach to link data from the time of injury, the subsequent medical record, and real time patient-based outcomes assessment years after injury. In this context, the proposed study encompasses the entire timeline from point of battlefield injury to eventual perceived physical and psychological recovery. Findings from this study stand to characterize the physical and psychological impact of extremity vascular injury and guide military providers, patients and their families as they cope with recovery from extremity injury. Finally, in characterizing the relationship between the SMFSA and the SF-36 surveys, this study promises to provide novel insight in to a long suspected, but never quantified, relationship between quality of limb and quality of life; a finding that would impact the management of military and civilian extremity injury worldwide.

What was the impact on other disciplines?

Nothing to Report

What was the impact on technology transfer?

Nothing to Report

What was the impact on society beyond science and technology?

Nothing to Report

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Nothing to Report

Actual or anticipated problems or delays and actions or plans to resolve them

- Technology support staffing vacancies at the USISR resulted in delays updating and/or accessing the GWOT2 database. Temporary workarounds have been utilized while awaiting new staff hires to be completed.

- Significant delays were incurred waiting for protocol approval involving the VA /USAISR data sharing collaboration. Ultimately, the collaboration was removed from the protocol to facilitate approval from IRB allowing continuation of the project. Continued legal opinion is being sought to determine if a future collaboration is possible.

Changes that had a significant impact on expenditures

Nothing to Report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

To date 31 amendments and 35 protocol versions have been submitted and approved by Brooke Army Medical Center IRB. Most recently amendment #31 was submitted to add and remove personnel due to staffing changes. This amendment was approved in January, 2016. The protocol was also approved by the MRMC HRPO office in January 2016.

6. PRODUCTS:

- **Publications, conference papers, and presentations**
 - Mid-term, amputation free survival and patient based outcomes following wartime vascular injury-The American Association for the Surgery of Trauma 18-21 September 2014, podium presentation
 - REBOA-Clinical Use and Update for Vascular Wartime Injuries-Trauma Rounds and Symposium at the Aberdeen Royal Infirmary, 7 November 2013
 - Use of the Short Musculoskeletal Function Assessment for Assessing Limb-Specific Outcomes Following Extremity Vascular Injuries-Society for Military Vascular Surgery and Peripheral Vascular Surgery Society, 30 January 2014, podium presentation
 - Mental health co-morbidities of service members with extremity vascular injuries acquired in Iraq and Afghanistan, Society for Trauma Nurse, 2-4 April 2014, poster presentation
 - Vascular discharge education and follow-up care subsequent to wartime vascular trauma; Presented in San Antonio, TX, May 2014
- **Journal publications.**
Nothing to Report
- **Books or other non-periodical, one-time publications.**
Nothing to Report
- **Other publications, conference papers, and presentations.**
Nothing to Report
- **Website(s) or other Internet site(s)**
Nothing to Report
- **Inventions, patent applications, and/or licenses**

Nothing to Report

- **Other Products**
Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: Col Todd E. Rasmussen, MD, FACS
Project Role: PI
Nearest person month worked: 2
Contribution to Project: Col Todd E. Rasmussen is the former PI of the award.

Name: MAJ Zachary M. Arthurs, MD
Project Role: PI
Nearest person month worked: 16
Contribution to Project: MAJ Zachary M. Arthurs is the current PI of the award

Name: Thomas Evans
Project Role: Research Nurse
Nearest person month worked: 36
Contribution to Project: Mr. Evans assisted in developing the surveillance program design and continues to identify Service Members who incurred vascular injury. Mr. Evans also worked as lead on the VVR data scanning project.

Name: Joe Holguin
Project Role: Research Nurse Coordinator
Nearest person month worked: 11
Contribution to Project: Mr. Holguin assisted in developing the surveillance program design and identified Service Members who incurred vascular injury

Name: Shawn Dalle Lucca
Project Role: Technical Writer
Nearest person month worked: 9
Contribution to Project: Ms. Dalle Lucca provided technical writing expertise to GWOT Wartime Vascular Injury staff.

Name: Kira Long, MD
Project Role: Research Fellow

Nearest person month worked: 8
Contribution to Project: Dr. Kira Long assisted in developing the surveillance program design and identified Service Members who incurred vascular injury. She has left the study.

Name: Andrea Russell
Project Role: Research Nurse
Nearest person month worked: 36
Contribution to Project: Ms. Andrea Russell assisted in developing the surveillance program design and continues to identify Service Members who incurred vascular injury for inclusion in the study. Ms. Russell also oversees all regulatory records and submissions.
Funding Support: USAISR, Research Directorate

Name: Lee Ann Zarzabal
Project Role: Biostatistician
Nearest person month worked: 1
Contribution to Project: Ms. Zarzabal provided biostatistician and data analysis expertise to GWOT Wartime Vascular Injury staff

Name: Diane Miller
Project Role: Research Nurse
Nearest person month worked: 6
Contribution to Project: Diane Miller assisted in developing the surveillance program design and identified Service Members who incurred vascular injury. She departed to join another research study.

Name: Irma McNamee
Project Role: Research Nurse
Nearest person month worked: 36
Contribution to Project: Irma McNamee assisted in developing the surveillance program design and continues to identify Service Members who incurred vascular injury for inclusion in the study.

Name: Julie Cutright
Project Role: Research Nurse Coordinator
Nearest person month worked: 6
Contribution to Project: Assisted in reviewing Service Member records for inclusion in the study.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

The first Principal investigator, Col Todd Rasmussen, changed duty stations and he is now at Fort Detrick in Combat Casualty Care. MAJ Zachary Arthurs was selected to be the incoming PI of this effort by Col Rasmussen and took leadership of the protocol and award. sAdditionally, Maj Brandon Propper will assist MAJ Zachary Arthurs to lead the program. Both are vascular surgeons at SAMMC. Geneva sent a request for PI change from Col Todd Rasmussen to MAJ Zachary Arthurs to sponsor on 20 Feb 2014. Dr. Rose Ramos and COL Lorne Blackbourne are no longer working in support of this award. MAJ Zachary Arthurs assumed the role of PI in December 2013 after award PI change approval. As of 31JAN2017, MAJ Zachary Arthurs continues to be the PI for the award.

What other organizations were involved as partners?

Organization Name: USAF 59MDW/ST Chief Scientist's Office

Location of Organization: 2200 Bergquist Dr. Ste 1.

JBSA Lackland AFB, TX 78236

Partner's contribution to the project

- Facilities-project staff use the partner's facilities for project activities

Organization Name: United States Institute of Surgical Research

Location of Organization: 3698 Chambers Pass

JBSA Fort Sam Houston, Tx 78234-6315

Partner's contribution to the project

- Facilities-project staff use the partner's facilities for project activities
- Collaboration-Support for Ms. Andrea Russell's time in support of award.

Joint GWOT Vascular Initiative

12339071 / Forward Surgical/Intensive Critical Care
W81XWH-13-2-0014



PI: MAJ Zachary Arthurs, MD

Org: SAMMC / USAISR / The Geneva Foundation

Award Amount: \$2.16m

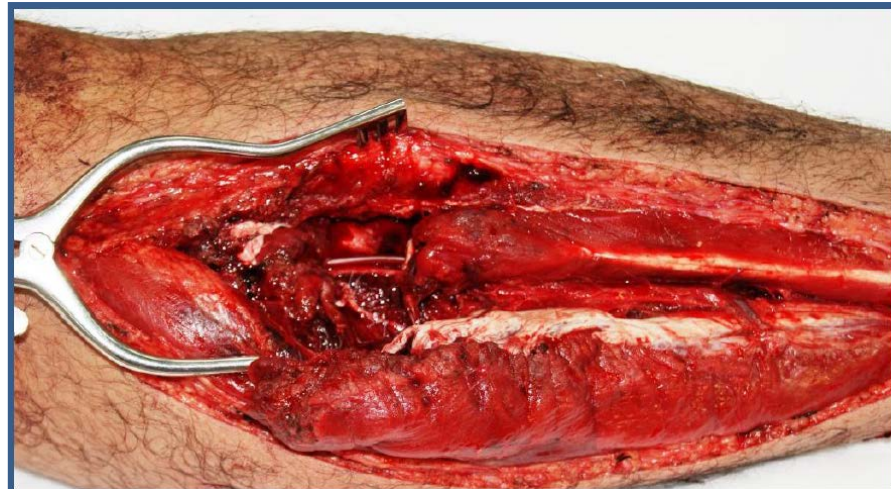
Study Aims

The objective of the proposed study is to initiate a large scale investigation of patient based outcomes following extremity vascular injury in the wars in Afghanistan and Iraq. In this effort, the study aims to provide novel information on amputation and return to duty rates as well as to characterize the relationship between eventual quality of limb and psychological recovery or well-being.

Approach

This study proposes to link acute injury and clinical management information from the Joint Theater Trauma Registry (JTTR) to authentic patient-based outcomes years following injury.

- **Objective 1:** Generate first patient-based outcomes data related to surgical intervention of vascular traumatic injuries for planning and programming.
- **Objective 2:** Translate criteria and strategies for selective vascular repair at key points in the joint theater trauma system.
- **Objective 3:** Identify additional factors influencing secondary amputation



Accomplishment: Patient Identification and database expansion continues as new data is obtained.

Timeline and Cost

Activities	CY14	CY15	CY16	CY17
Develop Surveillance Program Design				
Obtain IRB Approval and Hire Staff				
Enroll Patients and Complete Data Collection				
Conduct Data Analysis and Develop Strategies				
Disseminate Study Findings Through Peer-Reviewed Presentations and Publications				
Estimated Total Budget (\$2.16M)	\$701K	\$716K	\$524K	\$220K

Goals/Milestones

CY14 Goal – Design and Implement Study

- Develop Surveillance Program
- Obtain IRB Approval and Hire Required Staff

CY15 Goals – Continue to Expand Data Collection Efforts

- Implement Enrollment Plan
- Add Additional Staff as Required
- Adjust and modify Protocol as needed to improve enrollment success rates.

CY16 Goal – Complete Data Collection and Analyze

- Complete Data Collection

CY17 Goals

- Conduct Data Analysis and Develop Strategies
- Disseminate Study Findings Through Peer-Reviewed Presentations and Publications

Comments/Challenges/Issues/Concerns

- A No Cost Extension has been granted extending the period of performance until 30 June 2017. Timeline and Cost have been updated to reflect this.

Budget Expenditure to Date

Projected Expenditure- \$2.16M

Actual Expenditure: \$1.94M

Updated: 28 February 2017